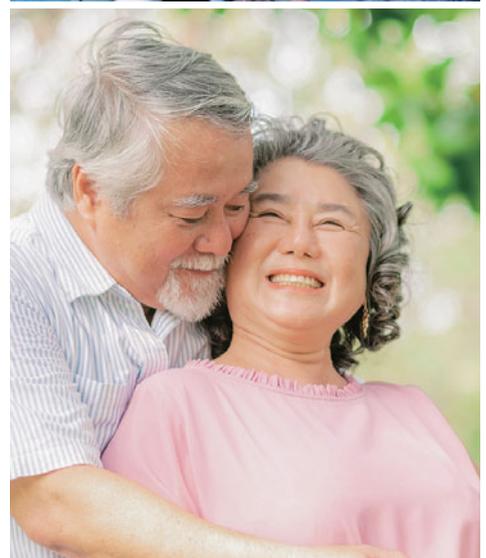
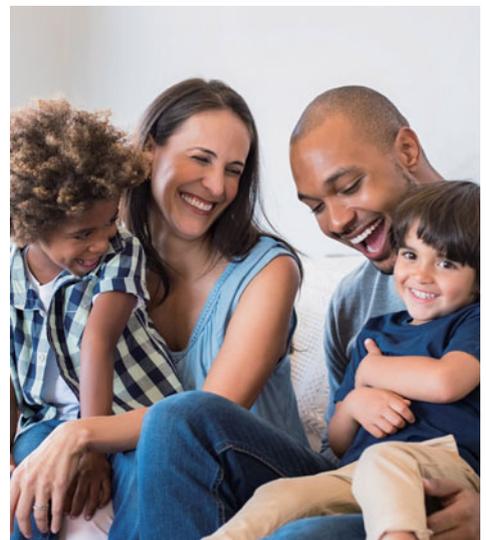




Sumitomo Dainippon
Pharma

Integrated Report **2020**

Innovation today, healthier tomorrows



Sumitomo Dainippon Pharma Co.,Ltd.

Securities Code 4506

On the Publication of the Integrated Report 2020

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 December 2019, we implemented a strategic alliance with Roivant Sciences and acquired a healthcare technology platform in addition to several promising development assets. In this Integrated Report, we will explain the significance of this strategic alliance. We will also explain quantitative and qualitative information on our CSR-based management initiatives that form the foundation for our value creation process and growth.

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

Information Disclosure Media

We disclose a variety of information so that our diverse stakeholders understand our business and initiatives. In addition to the investor relations (IR) and CSR content on our website, we have posted videos that introduce our roots and our thoughts on our business. We also publish a Corporate Profile and a Fact Book (published twice a year).

Corporate Site

<https://www.ds-pharma.com/>



IR Site

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



CSR Site

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



Integrated Report 2020



Fact Book 2020



Movie introducing Sumitomo Dainippon Pharma (Only available in Japanese)

<https://www.ds-pharma.co.jp/profile/profile/>



Roots of the company Part 1



Roots of the company Part 2



Hope of the company

Corporate Profile



Letters to Shareholders

(Only available in Japanese)



Editorial Policy

Applicable period

This report is based on the results for fiscal 2019 (April 1, 2019 to March 31, 2020). Some of the activities described were conducted in fiscal 2020.

Organizational scope

This report is based on the activities of Sumitomo Dainippon Pharma Co., Ltd. and its consolidated subsidiaries. Some of the information is based on Sumitomo Dainippon Pharma.

Reference guidelines

- IIRC, International Integrated Reporting Framework
 - Company-Investor Dialogue for Collaborative Value Creation compiled by the Ministry of Economy, Trade and Industry of Japan
 - GRI Sustainability Reporting Standards
 - ISO26000
 - International Financial Reporting Standards (IFRS) (applied from the fiscal year ended March 31, 2018)
- * The information in this report is presented on the IFRS core base unless otherwise specified.

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.

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Growing globally through a merger of two

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 21 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): Gastroprokinetic agent GASMOTIN®
- Cardiovascular: Vasodilator PRORENAL®
- Immunology/Inflammation: Long-acting anti-allergic agent EBASTEEL®



Aiming for a pioneering pharmaceutical company with a global presence

Establishment 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 / Nurturing a corporate culture imbued with an enterprising spirit

October 1, 2005

Establishment 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.)



1897

1984

2005

2006

Maximizing synergies from the integration

Establishing four mainstay products

AMLODIN® GASMOTIN®
PRORENAL® MERO PEN®

2007

2008

2009

First Mid-term Business Plan Solid Fundamentals

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

A pharmaceutical company that grew out of a chemical 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 MERO PEN®
- Oncology: Natural alpha interferon SUMIFERON®



Main New Products

(Japan)

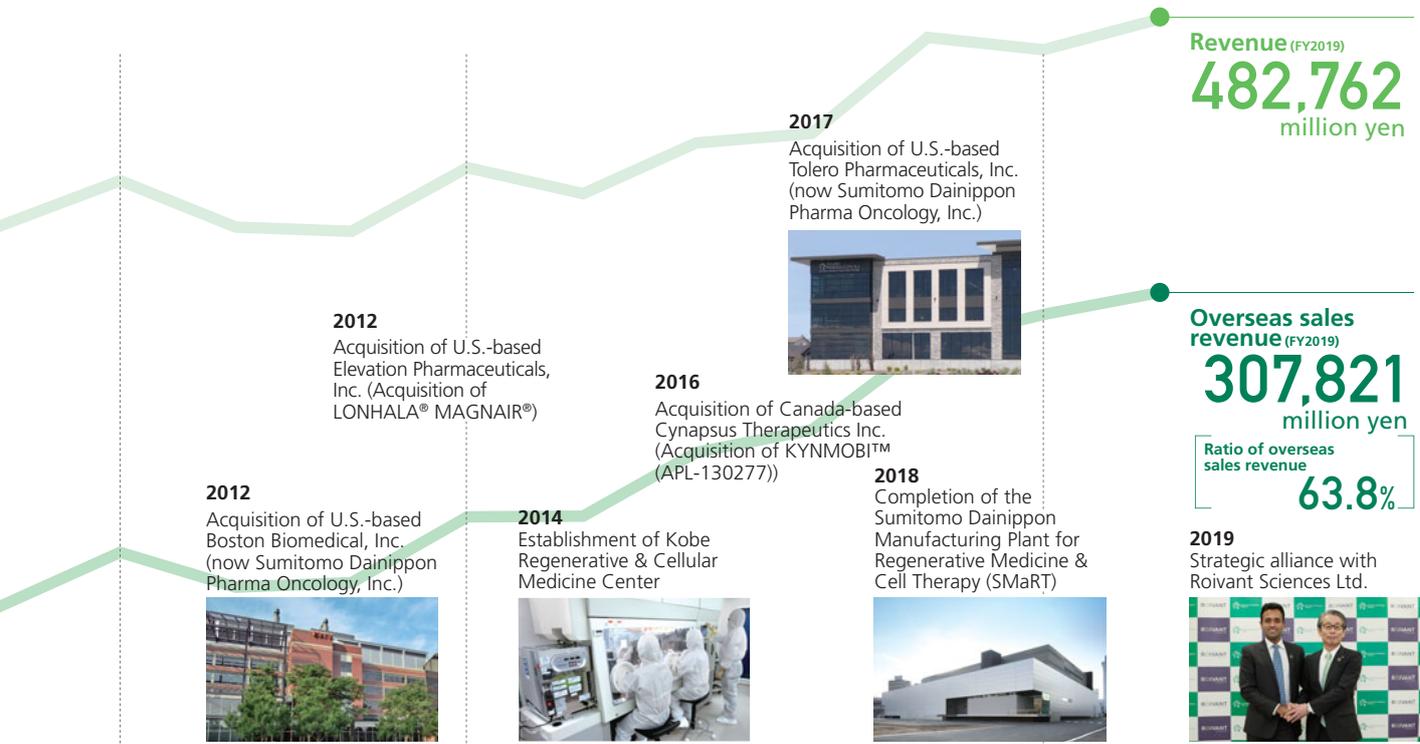
- Therapeutic agent for systemic fungal infection
AmBisome®

(Japan)

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



companies



2010 | 2011 | 2012

Second Mid-term Business Plan
Take off
Growth for LATUDA®
Full-fledged entry into oncology area

2013 | 2014 | 2015 | 2016 | 2017

Third Mid-term Business Plan
Sustained growth
Re-building and streamlining structure aimed at reinforcing business base in Japan
Expanding pipeline in Oncology area through M&As
Full-fledged entry into the Regenerative Medicine / Cell Therapy field

2018-2022 (FY)
Mid-term Business Plan 2022
Re-build Business Foundation
Prepare for the "Time for Change" and post-LATUDA revenue replacement
Reshape business foundation through the "establishment of growth engine" and "building of flexible and efficient organization"

(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®

(China)

- Atypical antipsychotic LONASEN®



(Japan)

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

(North America)

- Therapeutic agent for chronic obstructive pulmonary disease (COPD) LONHALA® MAGNAIR®
- Therapeutic agent for Parkinson's Disease OFF episodes KYNMOBI™

(China)

- Atypical antipsychotic LATUDA®

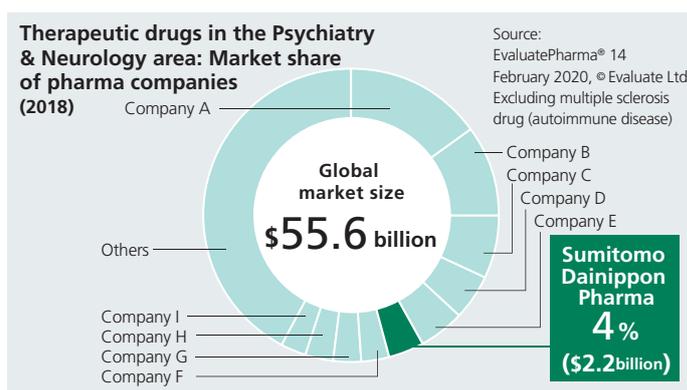


Strengthening our presence with innovative

Position in focus areas

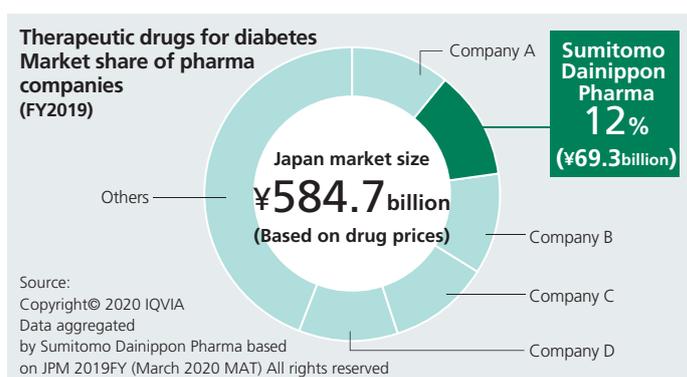
Psychiatry & Neurology area (Global)

Sumitomo Dainippon Pharma has established a top-class position in global market and is building a unique R&D pipeline in the psychiatric and neurological disorder therapeutic drug market, including atypical antipsychotic LATUDA®, which has global sales of approximately ¥190.0 billion. Both Sumitomo Dainippon Pharma and Sunovion Pharmaceuticals have a track record in continually creating new products and advanced research and development know-how cultivated in-house. By mutually complementing each other, we are striving to expand our pipelines with the aim of solving unmet medical needs.



Diabetes area (Japan)

In addition to Equa®, a DPP-4 inhibitor, and EquMet®, a combination agent, Sumitomo Dainippon Pharma has an extensive lineup of products which have different mechanisms of action, including Trulicity®, a GLP-1 receptor agonist, METGLUCO®, a biguanide, SUREPOST®, a glinide, and GLIMICRON®, a sulfonylurea, securing a leading position for sales in Japan in this area.



Japanese market

Psychiatry & Neurology area

TRERIEF®

Revenue: **¥16.2 billion**



Indications Parkinson's disease, Parkinsonism in dementia with Lewy bodies

Features Parkinson's disease drug with levodopa-enhancing effect

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® Tape

Revenue: **¥0.5 billion**

Launched in September 2019



Indications Schizophrenia

Features The world's first transdermal formulation approved for the indication of schizophrenia

About target disease

- Schizophrenia is a chronic disorder with various symptoms, including hallucinations, delusions, social withdrawal, decreased spontaneity, cognitive impairment, anxiety, and depression, that makes life, employment, and education difficult. The number of schizophrenia patients in Japan is approximately 800,000.

LATUDA®

Launched in June 2020



Indications Schizophrenia and bipolar depression

Features An atypical antipsychotic with antagonistic effects for dopamine D₂, serotonin 5-HT_{2A} and serotonin 5-HT₇ receptors and also acts as a partial agonist on serotonin 5-HT_{1A} receptors

About target disease

- Bipolar disorder is a chronic and serious disease characterized by repeated cycles of manic and depressive episodes. The number of bipolar depression patients in Japan is approximately 220,000. The main symptoms reported are depressed mood, loss of interest and joy, significant weight loss, insomnia, fatigue, feelings of worthlessness, decrease in ability to concentrate, and repeated suicide attempts.

• See LONASEN® Tape for schizophrenia

pharmaceutical products

North American market

Diabetes area

Trulicity®

Revenue:
¥30 billion



Indications Type 2 diabetes

Features

- Once-weekly glucagon-like peptide-1 (GLP-1) receptor agonist
- Single-use self injection pen (Ateos).

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 or injectable hypoglycemic agents are administered.

Equa®/EquMet®

Revenue:
¥17.1 billion



Indications Type 2 diabetes

Features

Equa®: DPP-4 Inhibitor
EquMet®: A combination agent that includes DPP-4 Inhibitor with metformin

About target disease

- See Trulicity® for type 2 diabetes

Psychiatry & Neurology area

LATUDA®

Revenue:
¥189.5 billion



Indications Schizophrenia, Bipolar I depression

Features

An atypical antipsychotic with antagonistic effects for dopamine D₂, serotonin 5-HT_{2A} and serotonin 5-HT₇ receptors and also acts as a partial agonist on serotonin 5-HT_{1A} receptors

About target disease

- Schizophrenia affects approximately 2.4 million people in the U.S.
- Bipolar disorder affects approximately 12.6 million people in the U.S.

APTiom®

Revenue:
¥23.4 billion



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.

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.

KYNMOBI™
(Generic name: apomorphine hydrochloride)
Scheduled for launch in September 2020



Indications OFF episodes in patients with Parkinson's disease

Features

A sublingual film formulation of apomorphine, a dopamine agonist

About target disease

- By 2030, it is estimated that approximately 1.2 million people in the U.S. and 10 million people worldwide will be living with Parkinson's disease.
- OFF episodes are the worsening or re-emergence of motor and non-motor symptoms otherwise controlled with appropriate drug therapy. 40–60% of Parkinson's disease patients experience OFF episodes.

Respiratory area

BROVANA®

Revenue:
¥34.5 billion



Indications Chronic obstructive pulmonary disease (COPD)

Features

A long-acting beta-agonist (LABA) delivered using a nebulizer

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.

**LONHALA®
MAGNAIR®**

Revenue:
¥2.9 billion



Indications Chronic obstructive pulmonary disease (COPD)

Features

A long-acting muscarinic antagonist (LAMA) delivered using the MAGNAIR Nebulizer System that applies eFlow® technology

About target disease

- See BROVANA® for chronic obstructive pulmonary disease (COPD)

Chinese market

Infectious diseases

MEROPEN®
(brand name in China: MEPEM®)
Revenue:
¥24.1 billion



Indications General infections, febrile neutropenia

Features

Standard therapy for severe infections, used in many countries

Note: Revenue for the Japan market is fiscal 2019 performance results based on Invoice price. However, revenue for Trulicity® is NHI price-based sales. Fiscal 2019 revenue for Equa® and EquMet® calculated starting from November 2019.

For the betterment of healthcare and fuller lives

Corporate profile (As of June 30, 2020)

Name	: Sumitomo Dainippon Pharma Co., Ltd.	Main banks	: Sumitomo Mitsui Banking Corporation Sumitomo Mitsui Trust Bank, Limited MUFG Bank, Ltd.
Establishment	: May 14, 1897	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)
Date of merger	: October 1, 2005	Businesses (Consolidated)	: 1. Manufacturing and sales of pharmaceuticals 2. Related businesses (Manufacturing and sales of food ingredients, food additives, veterinary medicines, and others)
Osaka head office	: 6-8, Doshomachi 2-chome, Chuo-ku, Osaka 541-0045, Japan TEL: +81-6-6203-5321 FAX: +81-6-6202-6028	Composition of revenue (Consolidated: the year ended March 31, 2020)	: Others 7.7% Pharmaceuticals 92.3%
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		
Fiscal year-end	: March 31		
Ordinary general meeting of shareholders	: June		

Major consolidated subsidiaries

(As of June 30, 2020)

		Establishment	Ownership	Fiscal year-end	Number of employees	Businesses
Japan	DSP GOKYO FOOD & CHEMICAL Co., Ltd.	Oct 1947	100%	March 31	202	Manufacturing and sales of food ingredients, food additives, chemical product materials, etc.
	DS Pharma Animal Health Co., Ltd.	Jul 2010	100%	March 31	92	Manufacturing, and sales of veterinary medicines, etc.
	DS Pharma Promo Co., Ltd.	Jun 1998	100%	March 31	47	Manufacturing and sales of pharmaceuticals, etc.
Overseas	Sumitomo Dainippon Pharma America, Inc.	Jul 2009	100%	March 31	59	Holding company of Sunovion Pharmaceuticals Inc. and Sumitomo Dainippon Pharma Oncology, Inc. and providing general and administrative service with these subsidiaries
	Sunovion Pharmaceuticals Inc.	Jan 1984	100%	March 31	1,494*1	Manufacturing and sales of pharmaceuticals
	Sumitomo Dainippon Pharma Oncology, Inc.*2	Nov 2006	100%	March 31	202	R&D in the oncology area
	Sumitovant Biopharma, Inc.	Oct 2019	100%	March 31	51	Implement oversight of Sumitovant group companies and formulation of potential business strategies for consideration of its group companies
	Myovant Sciences Ltd.	Feb 2016	54%	March 31	240*1	R&D in the women's health, prostate cancer area
	Urovant Sciences Ltd.	Jan 2016	75%	March 31	90*1	R&D in the urology area
	Enzyvant Therapeutics Ltd.	Jan 2016	100%	March 31	20*1	R&D in the pediatric rare diseases area
	Altavant Sciences Ltd.	Sep 2017	100%	March 31	12*1	R&D in the respiratory rare diseases area
	Spirovant Sciences Ltd.	Feb 2019	100%	March 31	15*1	R&D in the cystic fibrosis gene therapy area
	Sumitomo Pharmaceuticals (Suzhou) Co., Ltd.	Dec 2003	100%	March 31	764	Manufacturing and sales of pharmaceuticals

*1 Include employees of consolidated subsidiaries *2 As of July 1, 2020

of people worldwide

Our Mission

In October 2005, Sumitomo Dainippon Pharma Co., Ltd. was established 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.

Corporate Culture

After the merger of Dainippon Pharmaceutical Co., Ltd. and Sumitomo Pharmaceuticals Co., Ltd. in 2005, we focused on a fusion and harmony of minds to achieve synergies as quickly as possible. As a result, we have been able to nurture a corporate culture in which the positive elements that both companies possessed before the merger are even more pronounced, namely, diligence and integrity, respect for others, and trust.

Going forward, we will further increase the diversity of our organizations and human resources to establish a “culture of challenge” in which we identify changes in the environment rapidly and proactively try new things.

Establishing materiality and managing targets

Our approach to CSR-based management

Sumitomo Dainippon Pharma defines the practice of its Corporate Mission, “To broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide,” as CSR-based management. 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. Review and revision of materiality and targets is determined following deliberation by the Management Committee and shared with all the directors at the Executive Committee.

Our top priority sustainable development goals and targets

	<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>12.4 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>8.5 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>17.17 Encourage and promote effective public, public-private and civil society partnerships, building on the experience and resourcing strategies of partnerships.</p>

Materiality (Material issues for CSR-based management)

Materiality linked to value creation

—solving issues is important for our sustained growth



Main changes in materiality

- There are no changes in the area of “Materiality linked to value creation.” “Development of innovative products and healthcare solutions” referred to psychiatry & neurology, oncology, regenerative medicine/cell therapy, infectious diseases, and frontier business, but we have deleted the reference to specific areas given that we will also focus on other areas in addition to these five.
- In the area of “Materiality that forms the foundation for business continuity,” given growing global interest in human rights, we have made an adjustment to further address respect for human rights through all of our business activities, and divided “CSR procurement (respecting human rights)” into “Respecting human rights” and “CSR procurement.”

Materiality that forms the foundation for business continuity

—solving issues is essential for our sustained growth

<ul style="list-style-type: none"> Respecting human rights Corporate governance Compliance 	<ul style="list-style-type: none"> Risk management Fair and transparent corporate activities Corporate regulatory compliance, quality assurance and stable supply 	<ul style="list-style-type: none"> CSR procurement Health, safety, and welfare of employees Environmental initiatives
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Establishing materiality targets (qualitative targets)

The Management Committee deliberated multiple times and established targets for each materiality aimed at Sumitomo Dainippon Pharma's sustained growth and enhancing corporate value.

The present targets are a mix of Group-wide targets and targets in Japan, and we will continue to revise them going forward to create more appropriate targets based on our business strategy.

Target (qualitative targets) for materiality linked to value creation

Development of innovative products and healthcare solutions
Contributing to the development of science
<ul style="list-style-type: none"> • Continuous development of pharmaceuticals in areas with high unmet medical needs • Concentration on the three focus research areas, best in class focused on values and other areas • Contribution to precision medicine* • Promotion of Innovative R&D utilizing big data and digital technology • Promotion of network-based drug discovery • Development of healthcare solutions to respond to the future healthcare needs centered on areas where synergies with the pharmaceutical business can be expected
Work Style Innovation
<ul style="list-style-type: none"> • Improvement of productivity (work efficiency improvement, enhancement of individual capabilities) • Improvement of employee satisfaction (employee satisfaction enhancement) • Virtuous cycle in Work-life balance • Curbing of long working hours (overtime work, late-night work, holiday work)
Diversity & inclusion
<ul style="list-style-type: none"> • Creation of an environment where each employee is respected for their difference and can perform at their full potential • Promotion of active participation by female employees • Promotion of active participation by people with disabilities through appropriate placement
Training and development of employees
<ul style="list-style-type: none"> • Fostering of leaders (DSP Academy) • Promotion of company-wide education programs to enhance capabilities of individuals • Promotion of English proficiency enhancement toward globalization • Strategic allocation of human resources through talent management and acceleration of human resources development
Patient support and advocacy
<ul style="list-style-type: none"> • Information provision and communication support for patients and their families • Promotion of support activities through donations and cooperation with patients' associations • Strengthening of dissemination to raise awareness of diseases through our website
Local community contribution
<ul style="list-style-type: none"> • Promotion of social contribution / donations that lead to resolution of social issues • Promotion of charitable activities in local communities • Promotion of activities to support the development of the next generation
Contribution to global health
<ul style="list-style-type: none"> • Development of drugs to treat malaria and antimicrobial-resistant (AMR) bacterial infections • Strengthening of public-private collaboration on countermeasures against AMR and appropriate use of antibiotics • Promotion of public awareness-raising activities for health, hygiene, and nutrition
Initiatives to improve access to medicines
<ul style="list-style-type: none"> • Strengthening of response to requests for the development of unapproved and off-label drugs • Acceleration of provision of drugs at fair prices • Promotion of public awareness-raising activities with the aim of improving medicine-related literacy
Improvement of healthcare infrastructure in developing countries
<ul style="list-style-type: none"> • Support for capacity building of healthcare professionals, development of healthcare networks, etc. • Support for development of pharmaceutical regulations and supply chains in collaboration with local governments and international organizations
Measures to address falsified medicines
<ul style="list-style-type: none"> • Prevention of falsification of medicines • Detection of falsified medicines and illicit distribution

* Contribution to realization of more precise medical approach through understanding of pathology and pathogeny based on cutting-edge science and technology and patient stratification and prediction of treatment outcomes utilizing biomarkers.

Targets (qualitative targets) for Materiality that forms the foundation for business continuity

Respecting human rights
<ul style="list-style-type: none"> • Promotion of respecting human rights throughout all the value chain based on global trends • Promotion of initiatives in accordance with the United Nations Guiding Principles on Business and Human Rights • Formulation of the human rights policy as a global group policy
Corporate governance
<ul style="list-style-type: none"> • Pursuit of highly effective corporate governance • Establishment and appropriate implementation of an internal control system • Pursuit of diversity of the Board of Directors • Improvement of effectiveness of the Board of Directors • Ensuring the independence of management and protecting the interests of minority shareholders
Compliance
<ul style="list-style-type: none"> • Thorough compliance with all relevant laws and regulations and prevention of corruption • Practice of the Declaration of Conduct and Compliance Standards • Appropriate operation of compliance promotion system and establishment of rules • Improvement in the effectiveness of the whistle-blowing system
Risk management
<ul style="list-style-type: none"> • Appropriate implementation of risk assessment • Rebuilding of business continuity plans (BCP) • System development, training and seminars for anticipated risks • Proper information management (management of confidential information, internal information and personal information, information technology security)
Fair and transparent corporate activities
<ul style="list-style-type: none"> • Proactive disclosure of information • Ensuring transparency on relationships with healthcare professionals and patients associations • Sincere corporate activities contributing to the enhancement of stakeholder engagement • Respect for intellectual property • Promotion of appropriate provision of information based on scientific grounds
Corporate regulatory compliance, quality assurance and stable supply
<ul style="list-style-type: none"> • Ensuring appropriateness of quality assurance and pharmaceutical affairs as well as data integrity • Practice of pharmacovigilance by centralized management of safety information and implementation of timely safety measures • Prevention of occurrence of drug-induced suffering • Promotion of proper use by provision of appropriate information • Continuation of three Ss (safe operations, sound quality and stable supply) • Strengthening of supply chain
CSR procurement
<ul style="list-style-type: none"> • Assessment of supplier business activities • Implementation of fair and transparent transactions based on procurement ethics
Health, safety, and welfare of employees
<ul style="list-style-type: none"> • Practice of the declaration of "Health Innovation" • Promotion of employee health management and mental health • Prevention of excessive working hours • Occupational health and safety activities, prevention of occupational accidents
Environmental initiatives
<ul style="list-style-type: none"> • Contribution to building a low-carbon society • Contribution to building a recycling-oriented society • Contribution to biodiversity conservation • Chemical substance management • Promotion of Environmental communications

Establishing a Vision for 2033

Changes in environment surrounding pharma

Going forward, it is thought the pharmaceutical industry will face a Time for Change. Pharmaceutical companies must adapt to diversifying healthcare needs that include not only the creation of innovative new drugs but also making preventative medical care more widely available and contributing to global health. This will require the establishment of non-conventional new business models.

Anticipated changes over the next 15 years

Society

- 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

Healthcare/ Healthcare System

- 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

Healthcare Industry

Solution to unmet medical needs

- Pharmaceutical products remain at the core of solutions
- Digital technologies become available
- Preventive medical care becomes available

Goal and Vision 2033

In addition to becoming a global leader in its three focus research areas of Psychiatry & Neurology, Oncology, and Regenerative Medicine / Cell Therapy, Sumitomo Dainippon Pharma will work to develop best in class* pharmaceuticals with an emphasis on value, as well as Frontier business where we expect synergies with the pharmaceutical business, aspiring to establish a position as a “Global Specialized Player” in 2033.

* Best in class: There are existing drugs, but new drugs that have a clear advantage over the existing drugs. We also expect best in class products acquired through the strategic alliance with Roivant Sciences as a growth engine.

Vision

**For Longer and Healthier Lives:
We unlock the future with cutting-edge
technology and ideas**

Position we aspire to establish in 2033

Global Specialized Player

Pharmaceuticals + Solutions



Global leader in 3 areas



Best in class focused on value

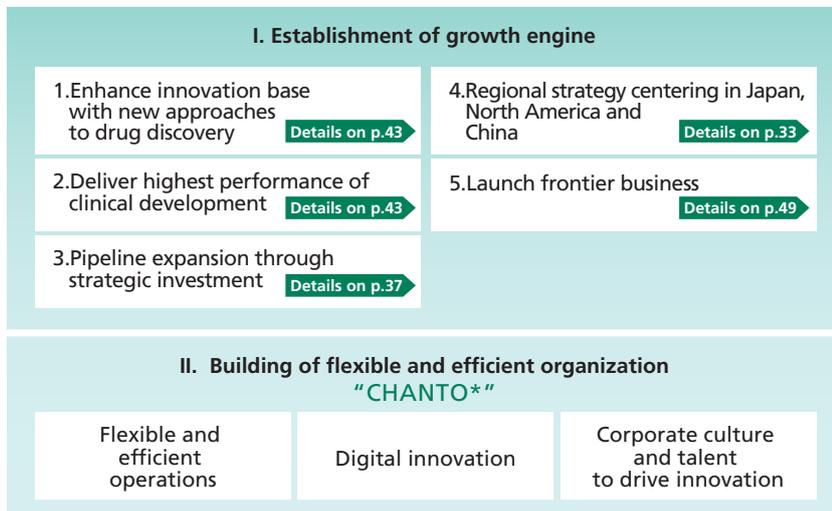
Mid-term Business Plan 2022

Sumitomo Dainippon Pharma will continue concentrating on research and development in its three focus areas, preparing for the post-LATUDA situation (after the expiration of the exclusive marketing period for LATUDA® in the U.S.). At the same time, we will improve the probability of success and efficiency of research and development leveraging biomarkers and big data, and enhance our innovation base with new approaches to drug discovery to establish a growth engine. In addition, assisted by digital innovation, we will build an organization and human resources capable of identifying changes in the external environment and adapting in a proactive flexible manner to reinforce the organizational

base to support the growth engine.

Moreover, we have implemented a strategic alliance with Roivant Sciences and acquired shares of Sumitovant and its five subsidiaries from Roivant in order to strengthen post-LATUDA sustained growth. The alliance has enabled us to acquire multiple pipelines with development compounds that are expected to be launched by fiscal 2022, and have potential to be blockbusters. In addition to those pipelines, we have acquired healthcare technology platforms (DrugOme and Digital Innovation) and the associated human resources that will be able to realize enhancement of the Group's overall productivity and acceleration of digital transformation.

Basic Strategies



* 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

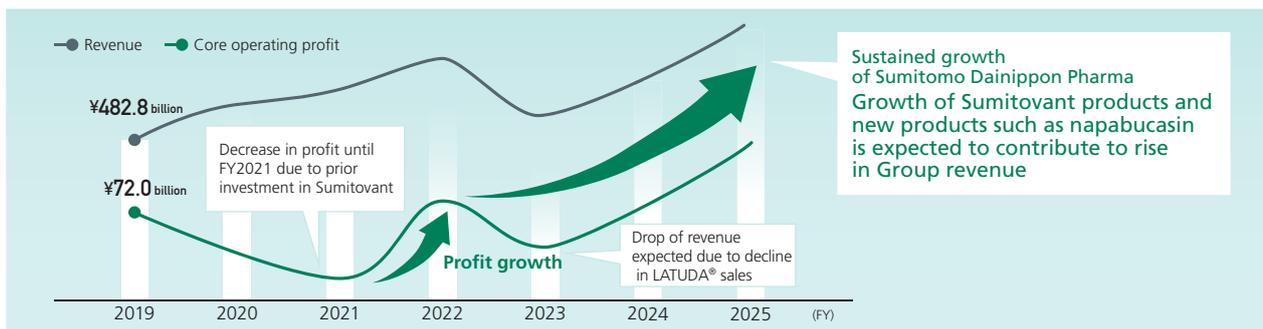
Financial goals and dividend policy (Plan to review during FY2020)

FY2022 business goals
 Revenue ¥600 billion
 Core operating profit ¥120 billion

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

Business performance outline after FY2020



We will continue to accelerate the Sumitomo Dainippon Pharma Group's business innovation activities to prepare for success following the period of LATUDA[®] market exclusivity in the U.S.



In fiscal year 2019 (year ended March 31, 2020), Sumitomo Dainippon Pharma embarked on a strategic alliance with Roivant Sciences, Inc. ("Roivant"), further accelerating our medium- to long-term growth strategy in preparation for post-LATUDA success.*1

Here, we discuss the Group's achievements for fiscal 2019, a year that became a turning point, and the future business performance outlook.

*1 After expiration of the exclusive marketing period for LATUDA[®] in the U.S.

Hiroshi Nomura

Representative Director, President
and Chief Executive Officer

Q1 How would you rate the Group's achievements and business performance in fiscal 2019 (year ended March 31, 2020)?

A1 We experienced growth in revenue but a decline in profit due to an increase in expenses associated with the strategic alliance. However, we made steady progress on our strategy aimed at post-LATUDA success.

The most significant development for the Group in fiscal 2019 was the strategic alliance with Roivant. As a result of this agreement, we acquired a pipeline with multiple development compounds, including relugolix and vibegron, late-stage development assets that are potential near-term blockbuster products. This kind of opportunity to acquire a very promising pipeline in one go is extremely rare, so it can be described as a significant achievement. In addition, Sumitomo Dainippon Pharma acquired two healthcare technology platforms, called DrugOme and Digital Innovation that support Roivant's unique business model, together with the talent related to those platforms.



Going forward, by taking full advantage of these platforms, we will further accelerate digital innovation to achieve operational efficiency, including improvement of Group-wide productivity in areas such as research and development and marketing activities, etc.

The fiscal 2019 consolidated performance showed year over year growth in sales. However, core operating profit declined due to an increase in expenses associated with the consolidation of Sumitovant Biopharma Ltd., which was newly acquired through the strategic alliance with Roivant.

In the Japan segment, sales growth in the diabetes areas for products such as Trulicity®, Equa®, and EquMet® exceeded the decline in sales of long-listed products, resulting in a rise in revenue. In the North America segment, LATUDA® and APTIOM® sales contributed to increased revenue. In the China segment, sales increased primarily for MEROPEN® while marketing of LATUDA® also commenced. As a result, consolidated revenue amounted to ¥482.8 billion, up by ¥23.5 billion year over year.

Due to factors such as the new consolidation of Sumitovant, SG&A expenses increased by ¥3.8 billion year over year to ¥190 billion while R&D expenses were up ¥9.7

billion year over year to ¥92.6 billion. Consequently, core operating profit was ¥72 billion, down by ¥5.3 billion year over year.

In fiscal 2019, income taxes increased significantly owing to such factors as the reversal of deferred tax assets recognized in the United States in association with discontinuation of the global Phase 3 trial of napabucasin for pancreatic cancer. As a result, net profit attributable to owners of the parent company was ¥40.8 billion, down by ¥7.9 billion year over year.

Regarding R&D, in Japan, we obtained approval for LONASEN® Tape as the world's first patch formulation for the indication of schizophrenia, and began marketing that product in September 2019. We also obtained approval for LATUDA® for schizophrenia and bipolar depression, and we commenced marketing in June 2020. In addition, DSP-1181, which was created using artificial intelligence (AI), entered the clinical study for the planned indication of obsessive compulsive disorder (OCD). In the U.S., KYNMOBITM, for which we re-submitted an application for approval in November 2019, was approved as the first and only sublingual film formulation indicated for OFF

Message from the President

episodes associated with Parkinson's disease in that country in May 2020. We are currently preparing to start sales.

Although the global Phase 3 study of napabucasin for pancreatic cancer was discontinued, we have made steady progress on our strategy for post-LATUDA in the U.S. success, particularly through our strategic alliance with Roivant.

Financial Results for Fiscal 2019

(Billions of yen)

	FY2018	FY2019	YOY change (%)
Revenue	459.3	482.8	23.5 (5.1%)
Core operating Profit	77.3	72.0	-5.3 (-6.9%)
Operating profit	57.9	83.2	25.4 (43.8%)
Net profit attributable to owners of the parent	48.6	40.8	-7.9 (-16.2%)

Q2 Please tell us about the Group's plans for fiscal 2020 (year ending March 31, 2021).

A2 We expect a decline in profit due to the consolidation of Sumitovant, but the Group will focus on decisive launches of strong products to support future growth, and on establishment of an efficient marketing system.

In Japan, we aim to become the number one company in the Psychiatry & Neurology and the Diabetes areas. In the Psychiatry & Neurology area, we are working to penetrate the market early with the newly available product LATUDA® and focusing on sales expansion with LONASEN® Tape. In the Diabetes area, we are working to expand sales of Trulicity®, Equa®, and EquMet®, and we also applied for approval of imeglimin in July. In North America, besides working to expand the revenue and profit of LATUDA®, we will aim to penetrate the market early with KYNMOBITM. Meanwhile, in China, we will continue to focus on sales of MEROPEN® as well as boosting activities aimed at increasing sales of LATUDA® at an early stage. Through these initiatives,

we plan to increase fiscal 2020 consolidated revenue by ¥12.2 billion year over year to ¥495 billion.

We expect SG&A expenses to increase by ¥29 billion year over year due to such factors as the full-year recording of expenses at Sumitovant in addition to the increase in sales-related expenses, which include building commercial structures for the U.S. launches of relugolix and vibegron, and commencement of amortization of intangible assets associated with launches of new products such as KYNMOBITM. We also expect R&D expenses to increase by ¥10.4 billion year over year due to recording of expenses at Sumitovant. As a result of these factors, we forecast that core operating profit will fall by ¥39 billion year over year to ¥33 billion, and operating profit will decline by ¥59.2 billion year over year to ¥24 billion. We expect that net profit attributable to owners of the parent company will decline by ¥31.8 billion year over year to ¥9 billion.

Sumitomo Dainippon Pharma is further strengthening open innovation with universities, research institutions, and biotech companies, both in Japan and overseas, as an initiative to support ongoing growth. In addition to accelerating new drug discovery, we are also focusing efforts on developing our Frontier Business aimed at providing healthcare solutions utilizing non-drug treatments, including digital technologies.

We expect a significant decline in profit in fiscal 2020 due to factors such as the impact of consolidation of Sumitovant. However, the expenses associated with the alliance represent an essential upfront investment for sustained growth, even after expiration of the exclusive marketing period for LATUDA® in the U.S. We firmly believe that decisive market launches and penetration of products such as relugolix and vibegron will be a major force in supporting the Group's sustained growth.

Q3 Please tell us about the impact of COVID-19 on the Group's business.

A3 There was no marked impact on financial performance as of the first quarter of fiscal 2020. Looking ahead, we expect a negative impact on revenue, mainly in the U.S. segment, but anticipate the impact on core operating profit will be immaterial due a decline in SG&A expenses.

We are not seeing any significant impact on financial performance for the first quarter of fiscal 2020 due to the

COVID-19 pandemic. But, there have been some logistical impacts in areas such as in-person visits to medical institutions, provision of information in interviews by medical representatives, and progress on clinical studies. The forecasts for fiscal 2020 incorporate the negative impact associated with changes to insurance coverage due to the rising number of unemployed in the U.S.

Sumitomo Dainippon Pharma is not engaged in development of any COVID-19 treatment or vaccine. However, we have been implementing support activities, which include donating to research into this infectious disease, providing active pharmaceutical ingredients, and donating face shields and gowns to healthcare professionals via Japanese prefectural government agencies. We are also participating in the COVID-19 Research Database*² consortium as a collaborator.

In the area of clinical development, there have been impacts on some clinical studies owing to delays in patient registrations due to restrictions on going out, temporary suspensions of new patient registrations, and restrictions on visiting medical institutions. We have been continuing studies in accordance with all appropriate guidance in each country, such as that issued by the Food and Drug Administration (FDA) to put patient safety first. In order to minimize impacts, we are currently considering the schedules for future clinical study plans in collaboration with medical institutions in each country, and with contract research organizations (CROs). Due to the impact of this, the results of the global Phase 3 study of napabucasin for colorectal cancer, which had been scheduled to come out around summer 2020, have been delayed. While continuing to voluntarily restrict visits also in our marketing activities, we are focusing on providing and collecting information using Information Technology tools.

In production and distribution, there has been no impact to date on product supply at any of our production sites. Going forward, we will review and strengthen our supply chain as necessary by promoting further diversification and increases in the number of regions and countries from which we procure raw materials, while comprehensively considering various factors, including risk and cost.

Our current Business Continuity Plan (BCP) for production was prepared with a focus on maintaining stable supply primarily even in the event of natural disasters, such as earthquakes and typhoons, and fires. However, given the current situation, we will rework our BCP to take

account of the impact of an infectious disease pandemic on production and our response to such a situation.

*² A consortium that aims to make medical information databases in the U.S. available to researchers free of charge in order to support research on COVID-19

Q4 Please tell us about your approach to CSR-based management and the Group's material issues.

A4 We will continue to put our Corporate Mission into practice and contribute to the betterment of healthcare and fuller lives of people worldwide through our business activities.

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 July 2018, we identified the materiality (material issues) to be addressed through our business activities and the Management Committee has discussed and continually reviewed these issues in light of subsequent social changes, progress of our initiatives, and the feedback obtained through dialogue with stakeholders. In July 2020, we established "respect for human rights," which had been included in CSR procurement, as a separate material issue in light of mounting global interest in human rights and their importance for the Sumitomo Dainippon Pharma Group. Our Group, which engages in business around the world, supports the spirit of international fundamental principles of human rights (Universal Declaration of Human Rights, International Labour Organization (ILO) Declaration on Fundamental Principles and Rights at Work, etc.). We also observe laws on labor and employment in each country and region, in accordance with the UN Guiding Principles on Business and Human Rights. In this way, we will continue to fulfill our corporate social responsibility obligations by establishing appropriate working environments and respecting the human rights of our business partners, including suppliers in supply chains, and all of our stakeholders. In the recent update, we also set targets (quantitative targets) for each material issue.

While maintaining consistency of material issues and targets with our business strategy, including the Mid-term Business Plan, we will conduct regular reviews going

Message from the President

forward, and we will continue to establish Group-wide indicators from a more global perspective.

Q5 Please tell us about your perception of business opportunities and risks.

A5 We are broadening the scope of our R&D in order to effectively manage the risks of highly uncertain drug discovery.

Addressing risks that could threaten business continuity is vital in corporate management. We consider the biggest risks for Sumitomo Dainippon Pharma to be pharmaceutical industry-specific R&D risks. The Psychiatry & Neurology area, Oncology area, and Regenerative Medicine/Cell Therapy field, which are our focus areas, all entail high degrees of difficulty and uncertainty for R&D, in which new challenges are successively emerging due to the dramatic progress in technological innovation. When we consider business continuity, it is difficult to continually develop and launch innovative new drugs only in those areas in which we are seeking to develop first in class new medications. The addition of a best in class development pipeline focused on value, through the strategic alliance with Roivant, is also a strategy that will allow us to continually invest in new drug development in our research focus areas by dispersing and effectively managing our risks as a pharmaceutical company.

On the other hand, Sumitomo Dainippon Pharma has a track record in consistently creating competitive products, such as LATUDA®, in the Psychiatry & Neurology area, together with a wealth of drug discovery know-how, which includes utilization of cutting-edge technology (such as in

silico technology, biomarkers, iPS cells). In the Oncology area, we believe that we can attain a unique global position by focusing on R&D concentrated on the tumor microenvironment (intercellular interaction) and by taking advantage of our strong networks with academia and biotech companies. In the Regenerative Medicine/Cell Therapy field, besides the research credentials built up by Sumitomo Dainippon Pharma and Sumitomo Chemical, our robust networks with academia and biotech companies are a strength. We are proud to be a leader in such technologies as culturing and inducing differentiation of iPS cells. We also believe the utilization of cutting-edge technologies and open innovation increase the probability of success in research and development.

Obviously, there exist various business risks besides those relating to R&D. They include country risk, compliance risk, quality risk, natural disasters such as earthquakes and floods, and infectious disease pandemics. With regard to these risks, each business unit comprehensively ensures that risk management is implemented in accordance with the Group's basic policy, and acts in line with the Risk Management Policy whenever serious risks become manifest.

Q6 Please explain the changes with regard to revision of the business goals in the Mid-term Business Plan.

A6 We are working to formulate new medium- and long-term business goals in light of the increase in expenses associated with the strategic alliance with Roivant and the growth of the pipeline acquired.

Fiscal 2020 will be the third year of the Mid-Term Business Plan 2022 ("MTBP"). Because we have implemented new investments associated with the strategic alliance with Roivant, we are currently revising the business goals for fiscal 2022, the final year of the MTBP. We plan to release those business goals promptly after we obtain the results of the Phase 3 study of napabucasin for colorectal cancer.

In terms of how we view core operating profit from fiscal 2020 onward, profit will decline until fiscal 2021 due to the impact of upfront investments in Sumitovant. Even though profit will increase in fiscal 2022, it will fall again in fiscal 2023 due to expiration of the exclusive marketing period for LATUDA® in the U.S. We forecast that profit will



increase in and after fiscal 2024 on the back of growth in sales of Sumitovant products and of potential new products such as napabucasin.

Q7 Please tell us about the Group's approach to financial and capital strategy, and investment strategy.

A7 We aim to balance future sustained growth and financial soundness through upfront investments with consideration given to balance in business performance.

Under the MTBP, we established a strategic investment amount of ¥300 billion to ¥600 billion over the five years commencing in fiscal 2018, and we have already invested approximately ¥330 billion in the strategic alliance with Roivant. Currently, we are not planning any other large-scale investment projects. However, we will continue to consider investments in development pipeline acquisition for assets that can be expected to make contributions to revenue at an early stage, utilizing our existing marketing base. R&D investment has increased due to the strategic alliance with Roivant, and we expect that it will exceed ¥450 billion in five years, which is the forecast value in the MTBP. However, we plan to streamline R&D by making effective use of the healthcare technology platforms, such as DrugOme and Digital Innovation.

Of the ¥298 billion in interest-bearing debt at the end of fiscal 2019, we have decided to issue up to ¥120 billion in corporate hybrid bonds related to bridging loans of ¥270 billion procured as finance for the strategic alliance with Roivant with the aim of raising equity credit to maintain financial soundness over the long term. The balance is scheduled to be refinanced through loans from financial institutions.

Going forward, we will consider balance in business performance while focusing on clear allocation of resources for the future in order to achieve both sustained growth after expiration of the exclusive marketing period for LATUDA® in the U.S. and continued financial stability.

Q8 Please explain your policy on shareholder returns.

A8 Even though profit will decline during the period of the current Mid-term Business Plan, we will work to realize stable dividends going forward.

Sumitomo Dainippon Pharma's dividend policy is to increase dividends so as to reflect any improvements in business performance based on maintaining stable dividend payments. In accordance with that policy, although we expect a decline in profit in fiscal 2020, we will endeavor to maintain a stable dividend, and we plan to pay an annual dividend of ¥28 per share, which is unchanged from fiscal 2019. There is a possibility that we may have to revise that figure due to the potential impact of COVID-19.

As a result of upfront investments associated with the strategic alliance with Roivant, we expect profit to decline during the period of the MTBP. We set the five-year average payout ratio at 20% or higher during the MTBP, but the payout ratio will be at a high level, in excess of 100%, in fiscal 2020. We plan to review business goals for the MTBP, including the payout ratio, during fiscal 2020.

Q9 Do you have a fiscal 2020 message for stakeholders?

A9 We will utilize limited resources effectively as we strive for sustained growth and enhancement of corporate value.

Continuing the sustained growth of Sumitomo Dainippon Pharma, even after expiration of the exclusive marketing period for LATUDA® starting in the U.S. market in February 2023, is the single biggest mission that I have been given. Going forward, we will make the most effective use of limited management resources as we pursue sustained growth and enhancement of corporate value over the medium to long term while continuing to responsibly apply to management the feedback that we receive from stakeholders. We look forward to the ongoing support of all stakeholders.

Representative Director, President and Chief Executive Officer

Our efforts against COVID-19

Sumitomo Dainippon Pharma established the COVID-19 Countermeasure Headquarters on February 15, 2020 and took measures to prevent the spread of infection. Moreover, in this unprecedented situation, we have been minimizing the impact on the stable supply of pharmaceutical products and R&D, which are the responsibilities of a pharmaceutical company, as well as working on various social support activities.

1. Stable supply of pharmaceutical products

As of July 31, 2020 we do not have any immediate hindrance to product supply caused by COVID-19. We will monitor changes in the situation and take necessary actions while implementing infection control measures for our employees at our own plants and minimizing the impact when an infected person is detected. In Japan, demand for hand sanitizer has remained high, and we have continued making adjustments aimed at ensuring the supply of our products in this area.

2. Impacts on our R&D activities

We consider the safety of patients and the burden on medical institutions in accordance with the guidance on clinical study management issued by the regulatory authorities in each region, and we conduct clinical studies in cooperation with the investigators and Contract Research Organization (CRO). Although some studies suspended new patient enrollment, it is being resumed carefully as of late July 2020.

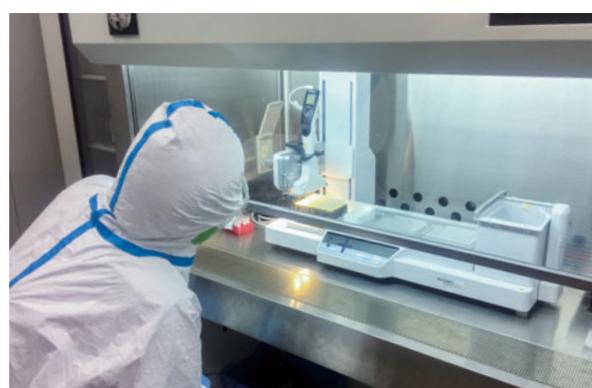
Going forward, we will continue to monitor all clinical studies we carry out and take appropriate responses.

3. Research support activities

Sumitomo Dainippon Pharma is not engaged in the development of COVID-19 treatments or vaccines. However, we have been providing support for research into COVID-19.

Donation to Kitasato Institute's Project for COVID-19

We donated ¥10 million to the Kitasato Institute's Project for COVID-19. This project aims to rapidly identify treatments for COVID-19 by screening approved pharmaceuticals for effects on the novel coronavirus.



Kitasato Institute lab screening approved pharmaceuticals

Providing drug substances to Basic Screening Plan for Drugs for Coronavirus Disease 2019

We are providing drug substances in response to a request from the Ministry of Health, Labour, and Welfare for the plan being implemented at the National Institute of Infectious Diseases in Japan.

Participating as a collaborator in COVID-19 Research Database

We are participating, as a collaborator, in the COVID-19 Research Database, a consortium investigating measures against COVID-19 which aims to provide researchers with free access to medical information databases in the U.S. to support research into COVID-19.

4. Support activities to prevent the spread of COVID-19

Japan

We donated 20,000 face shields to 15 prefectures mainly consisting of specified hazard prefectures in late April and May in cooperation with a general plastic manufacturer, Kawamura Kako Co., Ltd., headquartered in Ibaraki City, Osaka Prefecture to support infection control for healthcare professionals. In addition, we produced another 20,000

face shields with donations of more than ¥10 million from our domestic group board members, executive officers and employees and donated them to 36 prefectures.

Furthermore, we sourced 200,000 masks and 10,000 medical gowns through our Chinese subsidiary Sumitomo Pharmaceuticals (Suzhou) Co., Ltd., (“Sumitomo Pharmaceuticals (Suzhou)”) and donated them to local governments and groups in Japan.



Nationwide dispatch of face shields from Kawamura Kako

North America

Sunovion Pharmaceuticals Inc., our subsidiary in the U.S., has engaged in the following activities.

- Monetary donation to the Center for Disaster Philanthropy (CDP) COVID-19 Response Fund
- Donation of Personal Protective Equipment (PPE) to front line health workers in Massachusetts and New Jersey
- Food donations and financial support to several community organizations in collaboration with its food service vendor
- In Canada, establishment of a COVID-19 fund in collaboration with Innovative Medicines Canada, and in the UK, donations to a food bank in London



Donation of PPE from Sunovion

China

Sumitomo Pharmaceuticals (Suzhou) donated RMB 1 million (approximately ¥15 million) to the Chinese Red Cross Foundation. This donation was allocated to procurement of PPE and treatment equipment so that medical personnel could provide treatment more safely at a hospital in Wuhan, China.



Supplies being sent from the Chinese Red Cross Foundation to a hospital in Wuhan, China

5. Measures to prevent the spread of infection in Japan

As of July 31, 2020, Sumitomo Dainippon Pharma is taking the following measures in Japan.

Measures outside the Company

We only visit medical institutions that permit us to visit after taking infection control measures. We are also utilizing methods such as online interviews through a web conference system.

Measures for our employees

We are encouraging all employees at business offices in Japan to work from home. When they do come into the office, we recommend staggered working hours as well as adjusting the percentage of employees who are going into work to 50% or less.

In addition, Sumitomo Dainippon Pharma has paid expenses of up to ¥10,000 for all employees to enable the purchase of products that help with communication, exercise, and relaxation to maintain the physical and mental health of our employees as working from home continues.



Masayo Tada

Representative Director, Chairman

Upgrading global governance in response to large-scale strategic alliance

Sumitomo Dainippon Pharma regards corporate governance as one of the most important factors in ensuring corporate survival, and we have invested considerable effort into development of relevant rules and systems. For example, in order to improve the effectiveness of the Board of Directors, we have increased the number of outside directors based on the guidelines of the Corporate Governance Code as well as making efforts to select personnel with consideration given to a balance and diversity of knowledge, experience, and skills. Moreover, since fiscal 2015, we have been conducting annual evaluations of the effectiveness of the Board of Directors. In the results of the evaluation for fiscal 2019, we identified virtually no problems with regard to effectiveness and we confirmed sound functioning of the Plan-Do-Check-Action cycle, including an all-time high rating for “sufficient prior explanations for outside directors,” which was a problem identified in the fiscal 2017 evaluation. However, there were some new observations in such areas as “improvement of discussion aimed at enhancement of corporate value over the medium to long term,” “ideal future composition of the Board of Directors,” and “further enhancement of the quality of deliberations

of the Board of Directors,” and we will be striving to further enhance effectiveness going forward.

I expect that our next challenge in the area of governance will be strengthening the management and control systems of overseas subsidiaries in response to the advancement of global business activities. In conjunction with the strategic alliance with Roivant, Sumitovant and its subsidiaries are now included in the scope of consolidation. Sumitovant is a wholly owned subsidiary, but Myovant and Urovant, which are responsible for new product development and launches, are listed companies with other shareholders besides Sumitovant. A key goal is to determine how we will appropriately manage and control these overseas subsidiaries in accordance with the Sumitomo Dainippon Pharma Group’s management philosophy and business strategy. Taking into account the scale of investment and importance of the business, as well as the requirement for indirect control through Sumitovant while also protecting the interests of minority shareholders, it is clear that we will need more sophisticated governance that is at a completely different level than what we have had in the past. Going forward, I aim to further enhance the Sumitomo Dainippon Pharma Group’s governance, including strengthening of the monitoring system.

Heralding a new stage of globalization, we will further strengthen Sumitomo Dainippon Pharma Group-wide governance.

We will maximize synergies as a member of the Sumitomo Chemical Group while maintaining our independence.

A key aspect in the theme of Sumitomo Dainippon Pharma's governance involves considerations around the public listing pairing with Sumitomo Chemical. In recent years, there has been a trend toward eliminating publicly listed parent/subsidiary pairs due to such reasons as conflicts of interest and expansion of business synergies. However, from the perspectives of management efficiency, expertise, independence, and other considerations, Sumitomo Dainippon Pharma does not perceive an immediate need for any change in the current relationship with its parent company, which is that of a publicly listed parent and subsidiary pair. Even in relation to our recent strategic alliance with Roivant, although we did engage in prior consultation with our parent company, Sumitomo Dainippon Pharma made the decisions. Our parent company has always fully respected our intentions since the establishment of Sumitomo Dainippon Pharma, and we recognize that a high degree of management independence has been secured.

In addition, we believe that we can bring out the full potential of synergies as a Group within the current

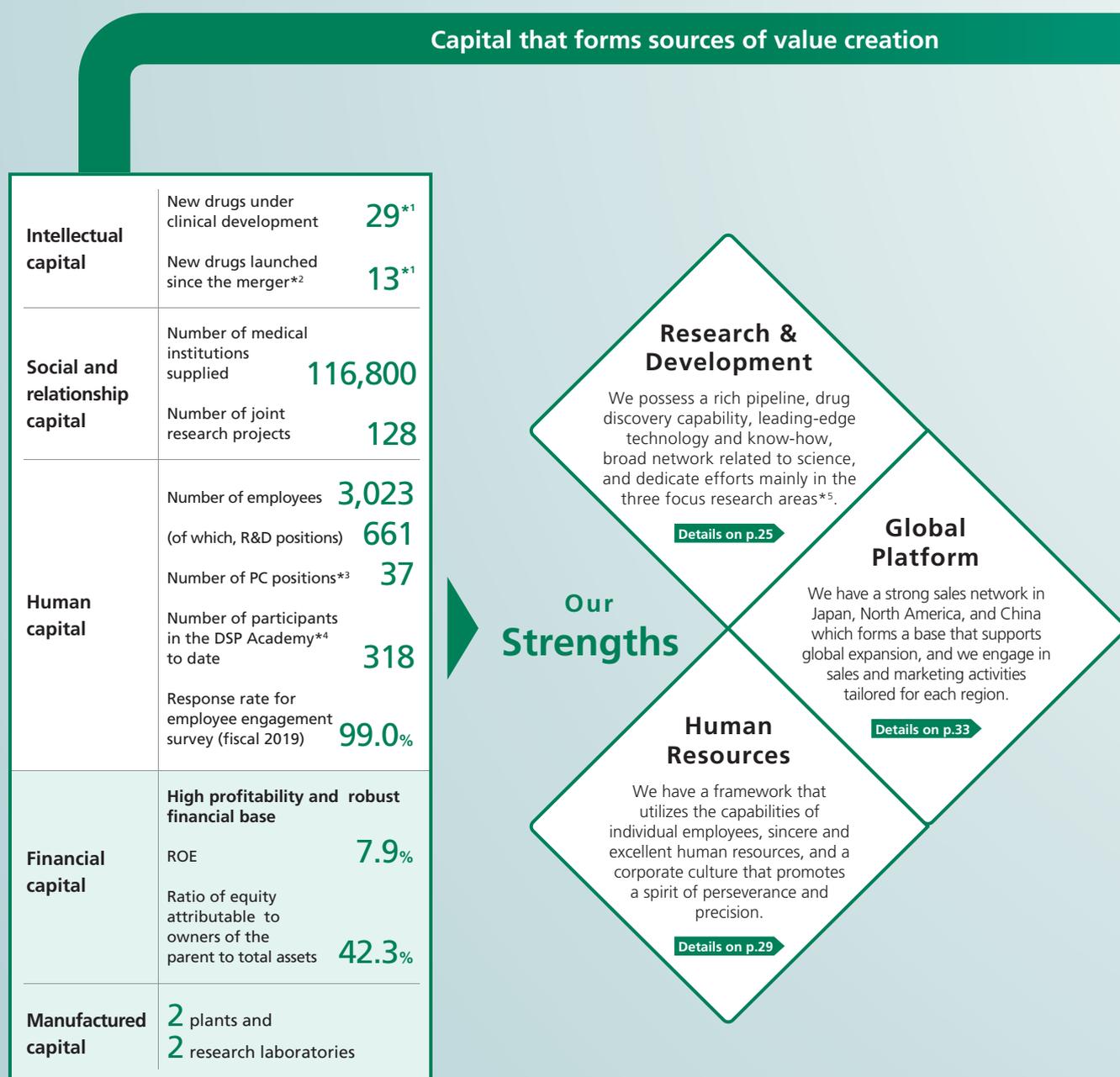
form of management. Sumitomo Dainippon Pharma has professional human resources in the life sciences. We anticipate being able to accelerate development of new medical technology and commercialization of healthcare solutions if we combine our strengths through collaboration with Sumitomo Chemical, which has many engineers who have mastered the skills and technologies for developing new equipment and devices, and we have initiated consideration of specific projects.

Naturally, the presence of a parent company should not adversely affect the interests of ordinary shareholders. That is why, in April 2020, we established the Supervisory Committee for Conflict of Interests between Group Companies, comprising only independent outside directors, to strengthen the framework for monitoring if fair transactions are being conducted with our parent company group. Going forward, Sumitomo Dainippon Pharma will continue to optimize synergies as a member of the Sumitomo Chemical Group in order to create new opportunities for growth while rigorously ensuring fair business activities.



Representative Director, Chairman

Utilizing our strengths to create the new drugs



As of March 31, 2020 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 30, 2020 *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.31) *5 Three focus areas for research: Psychiatry & Neurology, Oncology, Regenerative Medicine/Cell Therapy

patients need

Business activities

Value provided to society

Value chain

[Details on p.41](#)

Innovative Drug Discovery

(Number of compounds as of July 30, 2020)

- **Psychiatry & Neurology Area** New compounds under development: 10
- **Oncology Area** New compounds under development: 11
- **Regenerative Medicine / Cell Therapy Field** 6 projects
- **Infectious Diseases Area** 4 projects
- **Other Areas** New compounds under development: 6

Drug Development, Production, Sale, and Information Provision

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

Materiality linked to value creation

- **Work Style Innovation, Diversity & Inclusion** [Details on p.29](#)
- **Training and Development of Employees, Health and Safety** [Details on p.31](#)
- **Contributing to Global Health, Contributing to Local Communities** [Details on p.61](#)

Materiality that forms the foundation for business continuity

- **Strengthening the Corporate Governance, Risk Management, Compliance Systems** [Details on p.67](#)
- **Environmental Initiatives** [Details on p.64](#)

We have established "Materiality (material issues for CSR-based management)" for our business activities. [Details on p.9](#)

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

Strength: Research and Development

Aiming to be a global leader in three focus areas

Opportunities and risks in research and development

Opportunities

- There are high unmet medical needs in the three focus areas (psychiatry & neurology, oncology, and regenerative medicine/cell therapy) with significant impact on healthy life expectancy.
- Open innovation with academia and biotech companies is gaining momentum.
- Support from regulatory authorities, public institutions, governments and others can be actively utilized.
- The organizational structure to achieve optimum portfolio management on a global scale is in place.

Risks

- The focus areas of psychiatry & neurology and oncology are areas with a higher degree of uncertainty in research and development based on past performance, and there is a high degree of difficulty in research and development. As regenerative medicine/cell therapy is a new field, the rules on regulatory approval and drug price listing are not completely in place.
- If clinical development fails, there are significant losses due to soaring research and development expenses.
- There are global policy trends aimed at reducing medical and pharmaceutical expenses.
- Non-pharmaceutical disease prevention and treatment methods are emerging (which is an opportunity for Frontier business).

Research collaborations, in-licenses and acquisitions

Sumitomo Dainippon Pharma actively promotes strategic investment in acquisitions and in-licensing from a viewpoint of expanding the development pipeline.

We are also promoting research collaborations with research institutions, including universities, and biotech companies possessing innovative technologies.

Investment destination	<ul style="list-style-type: none"> • Apposite Healthcare Fund, L.P. Life sciences, healthcare services • Remiges BioPharma Fund, L.P. Pharmaceuticals research and development and other life sciences 	<ul style="list-style-type: none"> • DEFTA Healthcare Technologies, L.P. Leading-edge medical treatments and regenerative medicine, next-generation medical devices, and healthcare IoT/CT • MPM Oncology Innovations Fund Academia and growing early-stage companies that are developing new drug candidate compounds in the oncology area
External collaboration	<ul style="list-style-type: none"> • Kyoto University Project for drug discovery research focusing on the regulatory mechanisms of cell - cell interactions in tumor microenvironment (DSK Project) • The Kitasato Institute Joint Drug Discovery Research for AMR (KS-Project) • The Center for iPS Cell Research and Application (CiRA) (Kyoto University) • Hitachi Ltd. • Healios K.K. • Keio University • National Hospital Organization Osaka National Hospital 	<ul style="list-style-type: none"> • RIKEN • The Jikei University School of Medicine, Bios, PorMedTec • Carna Biosciences, Inc. • Colombia University, Harvard University, The Wistar Institute • Medicines for Malaria Venture (MMV) • Ehime University • NIBIOHN (National Institutes of Biomedical Innovation, Health and Nutrition) • MELTIN MMI • PATH

Note: For details: <https://www.ds-pharma.com/rd/research-alliances/>

Development pipeline (as of July 30, 2020)

Psychiatry & Neurology area New compounds under development: 10

Development products	Proposed indication	Development stage	Region	Launch target
SEP-363856	Schizophrenia	Phase 3	U.S.	FY2023
		Phase 1	Japan	TBD
SEP-4199	Bipolar I depression	Phase 2	U.S. Japan	TBD

Opportunities	<ul style="list-style-type: none"> The prevalence of psychiatric and neurological disorders is increasing due to aging and stressful society. The social and economic losses caused by psychiatric and neurological disorders are significant. A high percentage of patients experience insufficient effect with existing therapeutic drugs, and there are high needs for development of new drugs. We possess unique drug discovery platforms incorporating cutting-edge technology (in silico, biomarkers, and iPS cells, etc.) In addition to our track record of continually creating products, including the blockbuster LATUDA®, we possess a number of world-class development pipeline assets.
Risks	<ul style="list-style-type: none"> The psychiatry & neurology area is an area with a higher degree of uncertainty in research and development based on past performance. Due to lack of biomarkers for diagnosis and efficacy evaluation, research and development in this field is challenging with high uncertainty.

Oncology area New compounds under development: 11

Development products	Proposed indication	Development stage	Region	Launch target
relugolix	Prostate cancer	NDA submitted	U.S.	FY2020
napabucasin	Colorectal cancer	Phase 3	U.S.	FY2021
			Japan	FY2022
alvocidib	Myelodysplastic syndromes (MDS)	Phase 2	U.S.	FY2023*1

Opportunities	<ul style="list-style-type: none"> It is the disease area with the largest market (No. 1 cause of death for Japanese people*2). Unmet medical needs are high, and there is significant scope for special regulatory measures. Advanced technologies are being implemented in drug discovery research, clinical development, and the medical field (diagnosis and treatment), and the company's own technology platforms are becoming increasingly important for possessing an advantage in research and development. We are promoting initiatives aimed at discovery of ground-breaking new drugs based on expertise accumulated through continuing our unique drug discovery research focusing on the tumor micro-environment (inter-cellular actions and intra-cellular signals) and others. We are promoting new seeds searches and translational research through drug discovery based on strong collaborative networks within the Group and with academia and biotech companies.
Risks	<ul style="list-style-type: none"> The oncology area is an area with a higher degree of uncertainty in research and development based on past performance. The use of biomarkers for early-stage clinical assessment of compounds is becoming increasingly important, but translational research that links basic and clinical research is still developing. Precision medicine*3, which is the subdivision of a disease, limits the number of patients eligible for clinical trials, increasing the degree of difficulty of clinical development. The competition and progress in technological innovation are challenging, and the environment surrounding research and development is changing significantly.

*1 Premised on use of accelerated approval program (consultation with FDA planned going forward)

*2 Japanese Ministry of Health, Labour and Welfare website
<https://www.mhlw.go.jp/toukei/saikin/hw/life/life10/04.html> (in Japanese only)

*3 High-precision medicine based on understanding of pathology and etiology using cutting-edge scientific technology and patient stratification and treatment outcome prediction using biomarkers

Strength: Research and Development

Development pipeline (as of July 30, 2020)

Regenerative medicine / cell therapy field 6 projects

Projects	Proposed indication	Status	Region (planned)	Launch target
RVT-802	Pediatric congenital athymia	Under consideration to resubmit BLA	Global	FY2021 (U.S.)
Allo iPS cell-derived dopamine neural progenitor	Parkinson's disease	In progress: investigator-initiated clinical study Phase 1/2 study (Japan)	Global	FY2022 (Japan)*
Allo iPS cell-derived retinal pigment epithelium	Age-related macular degeneration (AMD)	In progress: clinical research Preparing to start clinical study (Japan)	Global	TBD
Allo iPS cell-derived photoreceptor	Retinitis pigmentosa	In progress: clinical research	Global	TBD
Allo iPS cell-derived neural progenitor	Spinal cord injury	In progress: clinical research	Global	TBD
Auto/Allo iPS cell-derived induced nephron progenitor cells	Kidney failure	In progress: pre-clinical study	Japan/ North America	TBD

Opportunities	<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, including the U.S., 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.
Risks	<ul style="list-style-type: none"> As Regenerative medicine/cell therapy is a new field, the rules including regulatory approval and drug price listing have not been fully established. Each product requires the establishment of different culturing methods, quality and safety assurance, and measures to reduce costs in production. Technological progress is rapid, requiring constant catch up.

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

Infectious diseases 4 projects

Projects	Joint research partners
Joint drug discovery research for infections caused by bacteria with antimicrobial resistance (AMR) (KS-Project)	Kitasato Institute
Further development of a new asexual blood-stage malaria vaccine candidate	Ehime University
Preclinical development project for a new malaria transmission-blocking vaccine (TBV)	Ehime University, PATH
Joint research for universal influenza vaccine	National Institutes of Biomedical Innovation, Health and Nutrition (NIBIOHN)

Opportunities	<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. As a result of COVID-19, a shared recognition has been reaffirmed that vaccines are essential for protecting human life and safety and are not only measures against infectious disease but also for national security.
Risks	<ul style="list-style-type: none"> Medical standards and insurance are undeveloped in emerging countries.

Other areas New compounds under development: 6

Development products	Proposed indication	Development stage	Region	Launch target
vibegron	Overactive bladder (OAB)	NDA submitted	U.S.	FY2020
relugolix	Uterine fibroids	NDA submitted	Europe U.S.	FY2021
	Endometriosis	Phase 3	U.S.	FY2022
imeglimin	Type 2 diabetes	NDA submitted	Japan	FY2021

Strength: Human Resources

Human resources for accelerating transformation

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.

In fiscal 2019, we held a company-wide workstyle reform lecture meeting and invited a world renowned instructor to give a lecture on tips for improving individual strengths based on the idea that enhancing the skills of each and every employee is essential in order to shift to higher productivity work styles. We also implemented hands-on, participation-based time management training to give employees opportunities for improving their own work styles and learning about methods and approaches for increasing productivity.

In order to reduce the risk of COVID-19 spread, Sumitomo Dainippon Pharma recommends the use of teleworking and staggered onsite work systems and has

implemented improvements to the network environment to support teleworking. Going forward, we will pursue even more flexible and high productivity work styles and aim to continue to create workplace environments where employees can exercise their full capabilities and achieve a work-life balance.

Main initiatives in FY2019

Implementation of training for officers

Participation in Telework Days 2019

- Promoted implementation focused on managers and supervisors

Curb long working hours

- Implemented briefings for managers and supervisors on the Labor Standards Act (regulations on maximum overtime, mandatory taking of 5 days of annual paid leave)
- Started Work Style Innovation Meetings at each work site for reviewing and improving tasks and work flow

Thoroughly managing work hours

- Encouraged improvement of the usage rate for paid leave
- Achieved the annual target rate (70%) for paid leave usage in fiscal 2019
- 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 aiming for zero smokers among employees, with resulting decrease in smoking rate to 13.8% in fiscal 2019 (16.6% in fiscal 2018)

Related SDGs



are a source of our competitiveness

Diversity & inclusion

Achieving work-life balance

At Sumitomo Dainippon Pharma, we consider that it is essential for all 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 their subordinates in both their careers and their broader lives, is extremely important in order to balance improving corporate competitiveness with achieving work-life balance.

In fiscal 2019, as the highest level of "Ikuboss," members of the HR Strategy Meeting* experienced the "Ikuboss Omurice (Japanese rice omelette topped with ketchup) Cooking Event," and the event was reported to



The Ikuboss Omurice Cooking Event (top)
Omurice cooked by President Nomura (right)

all employees of the company to demonstrate company's stance on promoting men's participation in housework. Many male employees participated in the "Men's Omurice Cooking Event" creating an opportunity for deepening workplace understanding of men's participation in housework.

* HR Strategy Meeting: a meeting in which all the Directors, some of the Executive Officers, and division heads as necessary take part to review and deliberate on human resources strategy from a company-wide perspective

Initiatives to promote LGBTQ understanding

Sumitomo Dainippon Pharma clearly states in our Code of Conduct that we do not discriminate on grounds of sexual orientation and gender identity. We also provide training for all employees to promote understanding of LGBTQ (lesbian, gay, bisexual, transgender, questioning, and queer). These initiatives have been recognized and obtained bronze certification in the Pride Index 2019. In addition, in April 2020, we introduced a same-sex partnership system, which provides equal treatment for same-sex partners and spouses in housing, special leave for weddings and funerals, and other programs.

Main initiatives in FY2019

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

Held LGBTQ training and seminars

Introduced same-sex partnership system

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



Obtained certification as a corporation that practices particularly outstanding health management based on the joint initiative to promote health implemented by the Ministry of Economy, Trade and Industry and Nippon Kenko Kaigi for four years in a row since 2017



Obtained certification by the Ministry of Health, Labour and Welfare as a corporation that provides excellent support for raising children in 2017



Obtained the highest "Eruboshi" certification (three stars) as a company making excellent progress implementing initiatives for the active involvement of female employees in 2017



Obtained bronze certification in 2019 Pride Index, an index that rates LGBT initiatives in the workplace

Strength: Human Resources

Supporting women's active participation

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.

In April 2019, women accounted for over 10% of managerial staff at Sumitomo Dainippon Pharma, achieving the goal set in 2016 ahead of schedule (12.2% as of April 2020).

Supporting active participation by people with disabilities through appropriate placement

Cocowork Co. Ltd., which was established in July 2018 to support independence of people with mental disabilities and accredited as a special subsidiary in May 2019, uses solar-powered hydroponics to cultivate leafy vegetables which are shipped to supermarkets and restaurants once harvested.

We have also set up massage work rooms at our head offices in Tokyo and Osaka, and employ people with disabilities who hold a masseur license (a national qualification). In addition, we have distributed iPads to hearing impaired employees to support communication in the workplace by using a speech to text recognition app.

As of June 1, 2020, our rate of employment of people with disabilities was 2.25%.

Related SDGs



Training and development of employees

DSP Academy, for training selected employees, and overseas training with open recruitment

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 and ambitious students, from young employees to mid-career employees as well as managers. One of the academy's programs is the "Management school" where the chairman fosters future top-level managers as the principal. 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.

The HR Strategy Meeting plays a major role in this development and selection of the next generation of leaders. The HR Strategy Meeting, which consists of all the Directors, some of the Executive Officers together with division heads as necessary, has been held regularly with over one hundred meetings during the past ten years. At each meeting, human resource-related issues are discussed, including work style reform, diversity and the selection of candidates for the next generation of leaders.

In addition, in fiscal 2017, we started an overseas training program with in-house 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 various employees possess which skills, assets, and capacities. Utilizing the talent management system, we encourage employees to take steps toward their own career planning and autonomous self-improvement. We also have supervisors and direct reports 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.

Starting from fiscal 2019, we introduced a many-sided diagnosis based on the belief that in order to further enhance the management skills of officers it is important to objectively identify the characteristics of the officers themselves and increase their trust and credibility among the people around them, including their supervisors and direct reports.

Developing human resources through application of Research Project system

In October 2017, we renamed our research organization the Drug Research Division and applied a “Research Project System” to accelerate the creation of innovative pharmaceutical products. Under this system, Project Leaders with budget authority are selected and are involved in the research project from the early stage through the later stages.

Project Leaders are selected irrespective of age and experience based on factors such as themes and enthusiasm and given budget authority and personnel

evaluation authority. The management of research projects with discretionary authority leads to the development of human resources.

Instilling group-wide awareness of CHANTO: delivery of best performance

Under the MTBP we are currently implementing, our basic policy is building a flexible and efficient organization instilled with CHANTO: Delivery of best performance. Our concept of “CHANTO” refers to the capability to continuously create and deliver innovation to people, while transforming our organization in flexible ways to adapt to changes in the world.

Whenever possible, we communicate this approach to the employees in the words of the President himself.



Related SDGs



Comment from Project Leader

In January 2020, a Phase 1 clinical study for DSP-1181 was initiated in Japan. DSP-1181 was created using Artificial Intelligence (AI) and development is planned for the indication of obsessive compulsive disorder. DSP-1181 has attracted attention because the exploratory research, which requires an industry average of four and a half years, was achieved in less than twelve months.

I have been driving DSP-1181 forward as Project Leader since October 2017. Due to the introduction of the Research Project System, we lead evaluation of the efficacy of compounds and decide which compounds to advance as a Project, which accelerated decision making. It's a very agile system, and I feel that it will also increase motivation toward drug discovery.

DSP-1181 is a compound that was created from the chance encounters of diverse people, ideas, and passions. I want to use my experience as Project Leader in drug discovery and clinical development going forward to deliver innovative new drugs to patients as quickly as possible.



Tatsuya Ishikawa

Clinical Research, Drug Development Division and Research Planning & Coordination, Drug Research Division

Strength: Global Bases

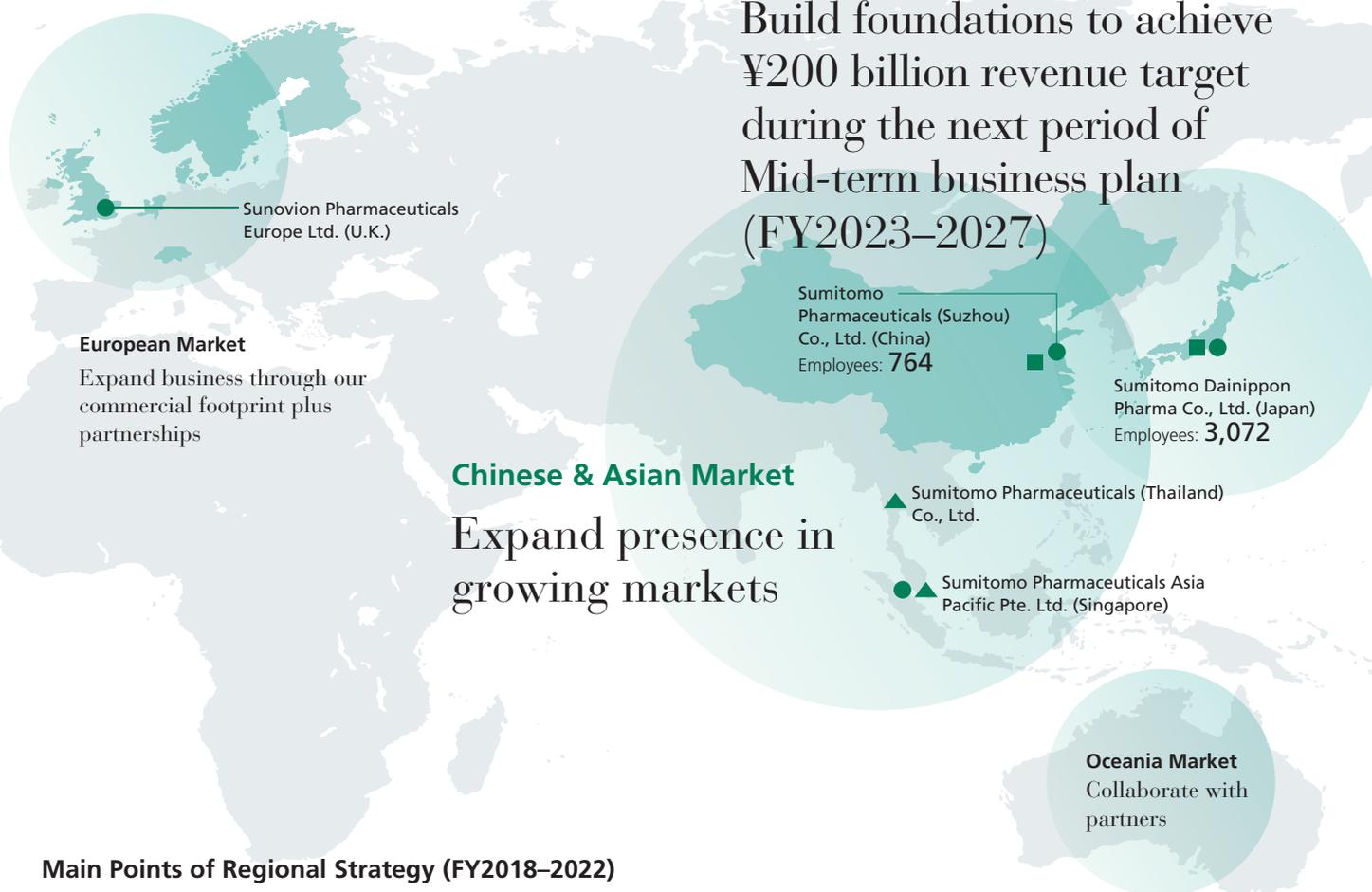
Established strong bases in Japan, North America

■ R&D departments ● Sales departments ▲ Regional headquarters information provision and collection base

Note: Number of employees as of June 30, 2020
(Sumitomo Dainippon Pharma Oncology Inc. established July 1, 2020)

Japanese Market

Build foundations to achieve ¥200 billion revenue target during the next period of Mid-term business plan (FY2023–2027)



Main Points of Regional Strategy (FY2018–2022)

Japanese Market

Transform to steady growth

- Maximize product value in Diabetes area (Trulicity®, Equa®/EquMet®, imeglimin)
- Maximize product value in Psychiatry & Neurology area (TRERIEF®, LONASEN® Tape, LATUDA®)
- 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 RETHIO®
- Optimize structure to collect and provide 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

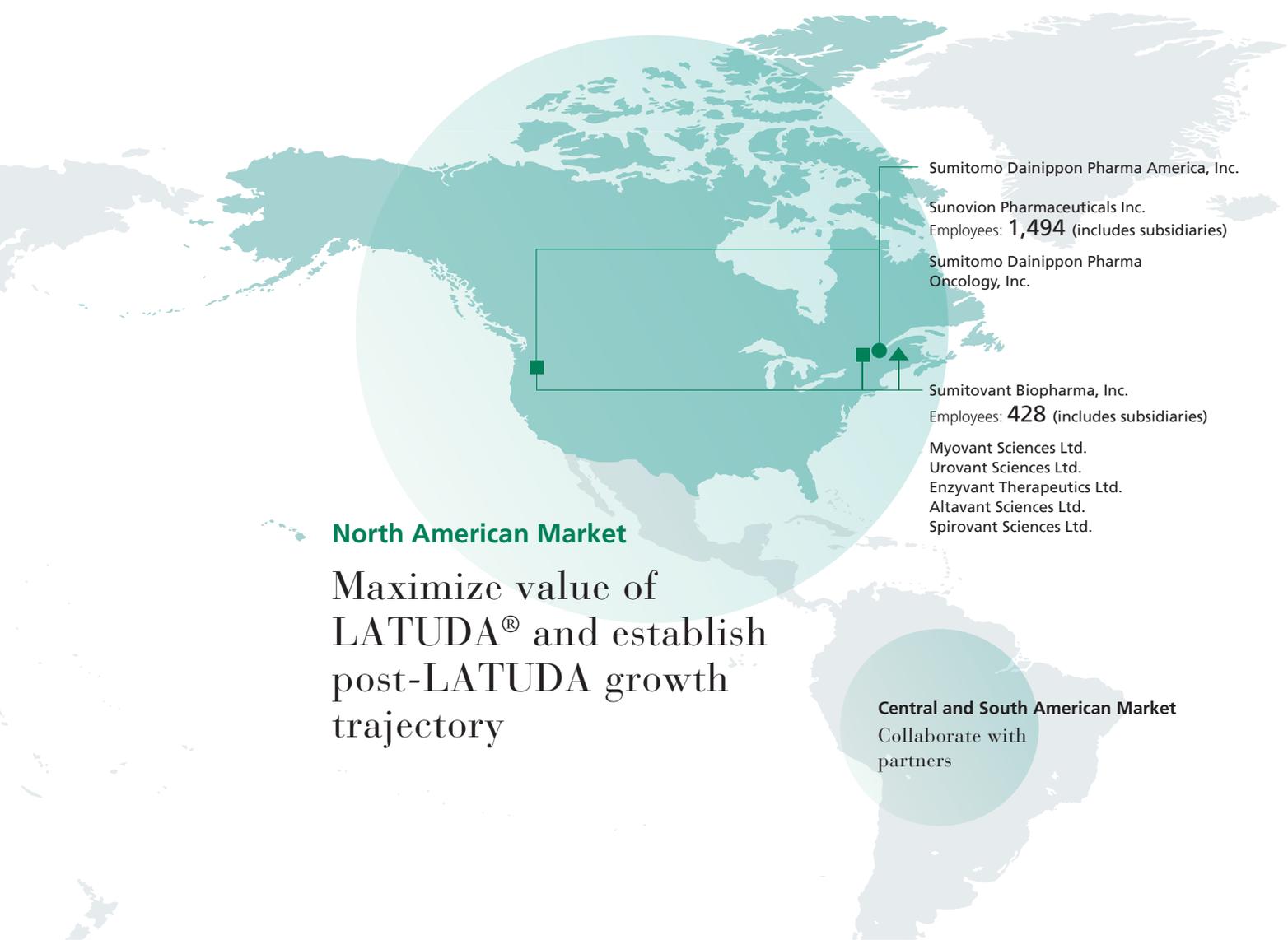
Maximize value of Psychiatry & Neurology and Respiratory products

- Maximize value of LATUDA®
- Accelerate development of SEP-363856
- Launch and maximize product value of KYNMOBI™ (launch scheduled in September 2020)

Establish business foundations for Oncology and other areas and maximize value of products

- Launch and maximize product value of relugolix, vibegron, and napabucasin

and China



North American Market

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

Sumitomo Dainippon Pharma America, Inc.
 Sunovion Pharmaceuticals Inc.
 Employees: **1,494** (includes subsidiaries)
 Sumitomo Dainippon Pharma Oncology, Inc.

Sumivant Biopharma, Inc.
 Employees: **428** (includes subsidiaries)

Myovant Sciences Ltd.
 Urovant Sciences Ltd.
 Enzyvant Therapeutics Ltd.
 Altavant Sciences Ltd.
 Spirovant Sciences Ltd.

Central and South American Market
 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 pipeline
- Pursue business opportunity in Regenerative Medicine/Cell Therapy and Frontier business

Further expand China business

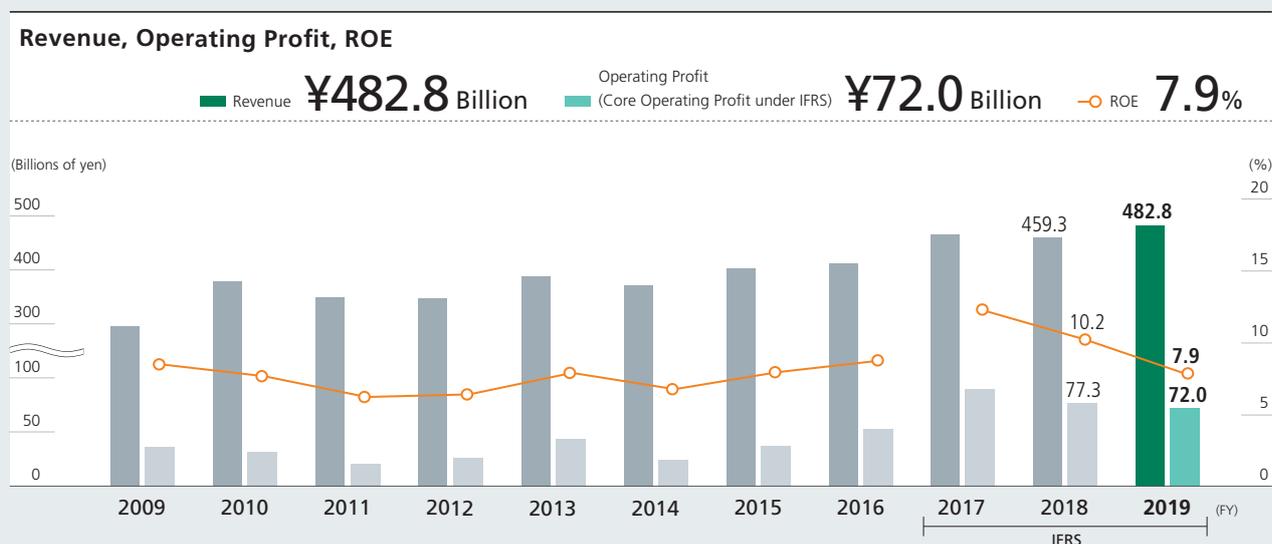
- Reinforce business infrastructure as the third pillar after Japan and North America
- Maximize revenue from MEROPEN[®]
- Ensure successful launch of new products (LONASEN[®] and LATUDA[®])
- Participate in global development

Reinforce business in Southeast Asia

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

Financial and Non-Financial Highlights

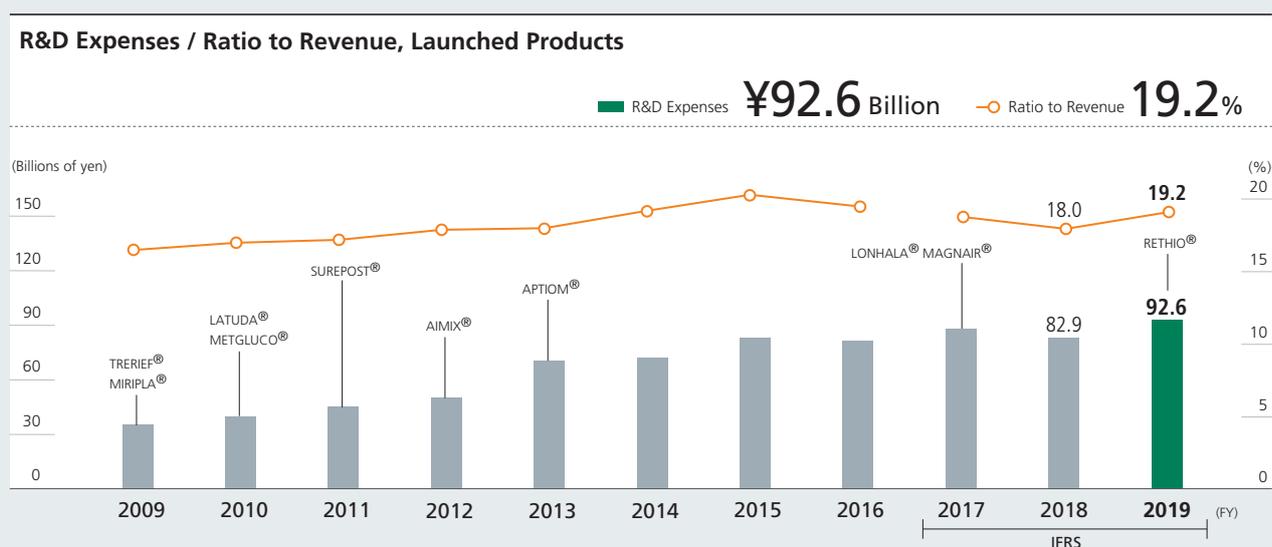
The Sumitomo Dainippon Pharma Group has adopted the International Financial Reporting Standards (IFRS) for preparing its consolidated financial statements from the fiscal year ended March 31, 2018.



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 core operating profit* in fiscal 2017 and all-time high revenue in fiscal 2019.

ROE was 7.9% in fiscal 2019 with a long-term goal of at least 10%.

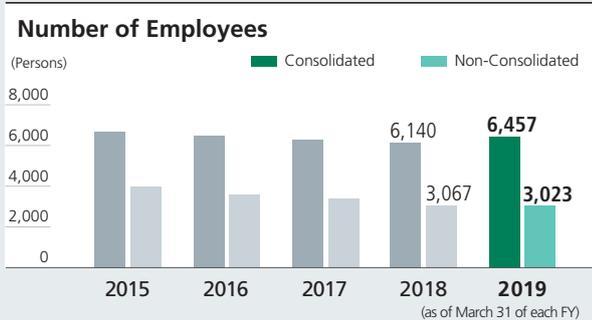
* Core operating profit is calculated by deducting from operating profit any gains and losses resulting from non-recurring factors that the Group designates.



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

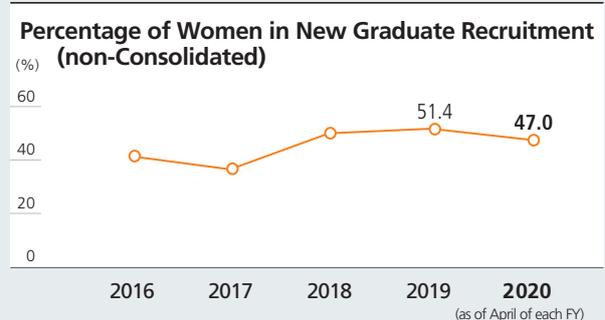
As a result, we have launched 13 new drugs since the merger in 2005. Going forward, we will continue to invest proactively in research and development.

Note: New drugs launched before fiscal 2009 are AmBisome®, REPLAGAL®, AVAPRO®, and LONASEN®.

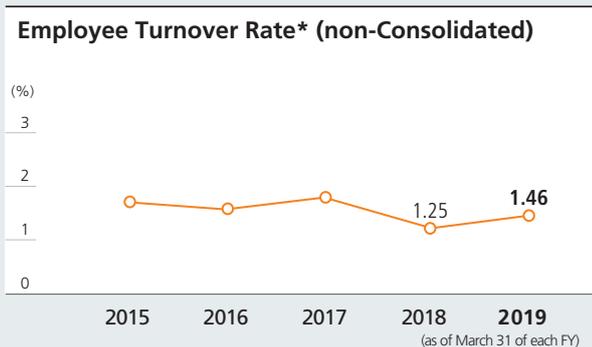


In fiscal 2018, the number of employees (consolidated and non-consolidated) decreased due in part to transfers associated with the establishment of DSP Business Partners Co., Ltd. and relocation and transfers of Genomic Science Laboratories associated with the establishment of the Bioscience Research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

Meanwhile, in fiscal 2019, the number of employees (consolidated) increased due to the new consolidation of Sumitovant and its subsidiaries.

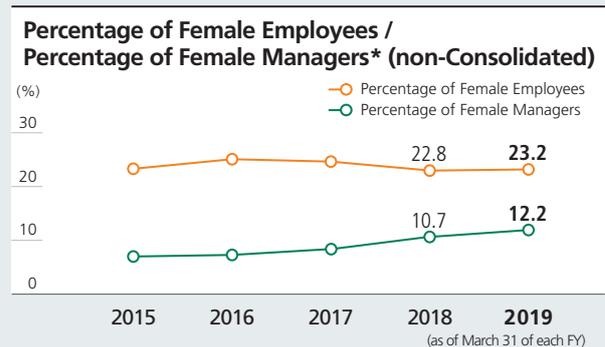


Our efforts to promote active participation by women, to create an environment that makes it easy for female employees to combine work with family life, and to support career development have been well received by students, and the percentage of women in new graduate recruitment has remained at a high level over the past few years.



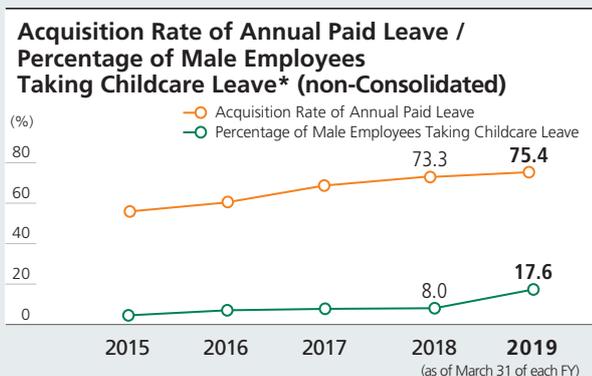
As a result of enhancing our systems and providing an employee-friendly environment, the employee turnover rate due to personal reasons at Sumitomo Dainippon Pharma has been at the 1% level for the past five years.

* Employee turnover rate due to personal reasons



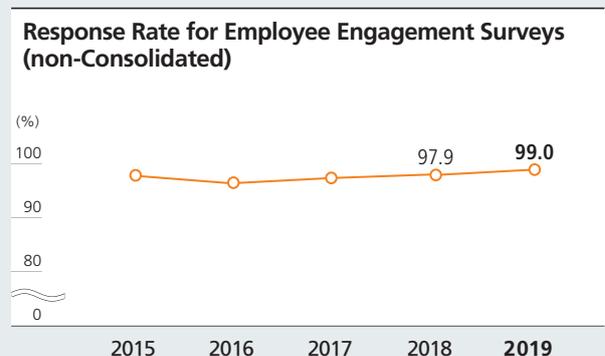
In fiscal 2018, the percentage of female employees decreased due to the secondment of many female employees to DSP Business Partners, but the percentage increased again in fiscal 2019. On the other hand, there was progress in female employee retention and career development, and the percentage of female managerial staff increased.

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



The acquisition rate of annual paid leave has increased due to the promotion of work style innovation.

In fiscal 2019, the percentage of male employees taking childcare leave was higher than in an average year. Also, at least 90% of employees took paternity leave (dubbed "Good Daddy Leave").



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.

Strategic alliance with Roivant Sciences



Shigeyuki Nishinaka

Senior Executive Officer
Global Corporate Strategy; Global Business Development;
International Business Management

Aims of the strategic alliance

Acquire candidates for post-LATUDA, early-stage pipeline, healthcare technology platforms, and talent for sustained growth and transformation of Sumitomo Dainippon Pharma Group

Key Challenges in MTBP 2022

- Expand post-LATUDA assets
- Expand pipeline by continued creation of innovative new drugs
- Meet needs for preventive medical care and for digital technologies
- Reinforce profitability of North America and Japan business, expand presence in China and Asia
- Enhance organizational capabilities to address changes in external environment

Significant reforms for achieving sustained growth

- Obtain potential near-term blockbuster products: relugolix and vibegron
- Gain access to multiple innovative clinical programs, including in gene therapy
- Improve R&D productivity and future pipeline expansion by leveraging the DrugOme platform
- Expand pipeline in Japan with multiple early-stage assets
- Introduce a framework and talent programs to accelerate the digital transformation of the group
- Cultivate a dynamic organizational culture

Q. What is the significance of this strategic alliance?

A. It is the foundation for achieving sustained growth with an eye on post-LATUDA success.

The exclusive marketing period for atypical antipsychotic LATUDA®, which had sales of ¥189.5 billion in North America in fiscal 2019, will expire in February 2023. Creating and obtaining post-LATUDA assets to offset the expected dramatic decline in revenue has been a major challenge. Sumitomo Dainippon Pharma has been pursuing opportunities for pipeline expansion to achieve sustained growth amid increasingly challenging future revenue projections.

Roivant Sciences, our alliance partner, is a biotech company established in 2014. Roivant’s business model involves acquiring and developing compounds for which other pharmaceutical companies have discontinued development for strategic reasons. This model is characterized by the establishment of subsidiaries called Vants for each therapeutic area or compound for swift and efficient development by small-scale organizations.

Through the strategic alliance, besides acquiring all of the shares of Sumitovant Biopharma, Ltd., a new

company to which five of Roivant's subsidiaries have been transferred, and obtaining multiple pipeline assets, Sumitomo Dainippon Pharma has acquired 11% of the shares of Roivant. The total investment is approximately ¥330.0 billion, which is our biggest investment ever. However, it is extremely significant that we have been able to acquire multiple late-stage development assets which are expected to grow. Profit will be on a downward trend until fiscal 2021, because expenses for steadily launching and maximizing sales revenue from these development assets will increase. However, we believe the alliance has provided a strong foundation*1 for minimizing the impact of decline in revenue from LATUDA® in and after 2023 and achieving sustained growth for Sumitomo Dainippon Pharma.

*1 Please see page 12 for Business performance outline after FY2020

Q. What pipeline assets have you obtained?

A. We have obtained ten development assets, which include potential near-term blockbuster products.

By acquiring the shares of five Roivant subsidiaries, Sumitomo Dainippon Pharma has been able to obtain multiple pipeline assets, including development assets expected to be approved by fiscal 2022 which could be



Vivek Ramaswamy (left), Founder & CEO of Roivant, and Hiroshi Nomura (right), Representative Director, President and CEO of Sumitomo Dainippon Pharma, agree on the strategic alliance

near-term blockbuster products.

We have particularly high hopes for relugolix and vibegron. An application for approval of relugolix for the indication of uterine fibroids was submitted in March 2020 in Europe and May 2020 in the U.S. An application for approval for the indication of advanced prostate cancer was also submitted in April 2020 in the U.S. and became eligible for priority review. In addition, there have been positive results in two Phase 3 studies for endometriosis as

List of main development assets of five subsidiaries acquired from Roivant (as of July 30, 2020)

Product	Indication	Phase	Characteristics	Originator	Development	Expected peak revenue ²
relugolix	Uterine fibroids	Submitted NDA (U.S.) Submitted NDA (Europe)	Oral, once-a-day, small molecule GnRH (gonadotropin-releasing hormone) receptor antagonist	Takeda Pharmaceutical Company Ltd.	Myovant	Large
	Endometriosis	Submitted NDA (U.S.)				
	Prostate cancer	Phase 3				
vibegron	Overactive bladder (OAB)	Submitted NDA (U.S.)	Oral, once-a-day, small molecule beta-3 adrenergic receptor agonist	Merck Sharp & Dohme Corp.	Urovant	Large
	OAB in men with BPH	Phase 3				
	IBS-associated pain	Phase 2				
RVT-802	Pediatric congenital athymia	Considering resubmission ³	Treatment of infants with congenital athymia by culturing thymus tissue obtained during cardiac surgery and implanting the cultured thymus tissue into quadriceps Granted Breakthrough Therapy, Regenerative Medicine Advanced Therapy, Orphan Drug designations and Rare Pediatric Disease by FDA	Duke University	Enzyvant	Small
rodatristat ethyl	Pulmonary arterial hypertension (PAH)	Phase 2	Prodrug of orally administered tryptophan hydroxylase (TPH) inhibitor	Karos Pharmaceuticals, Inc.	Altavant	—

² Large: Expect peak annual sales in global to be 50 billion yen or more; medium: 10-50 billion yen; small: less than 10 billion yen

³ Submitted in April 2019 in U.S., received Complete Response Letter (CRL) in December 2019, and considering resubmission

Strategic alliance with Roivant Sciences

well. An application for approval of vibegron for the indication of overactive bladder (OAB) was submitted in December 2019 in the U.S. A Phase 3 study for OAB associated with benign prostatic hyperplasia and a Phase 2 study for pain related to irritable bowel syndrome are also being conducted. We expect both relugolix and vibegron to be global blockbuster products when sales peak.

The fiscal 2020 sales forecast for LATUDA® is approximately ¥190.0 billion. We do not think that relugolix and vibegron can immediately offset the decrease in revenue after the expiration of the exclusive marketing period for LATUDA® in February 2023. However, we are striving to rebuild our business foundation using these best in class products and the first in class products created from our focus research areas as two growth engines.

Q. What have you achieved from the alliance other than pipeline expansion?

A. We have obtained the framework and talent to accelerate digital transformation.

Obtaining healthcare technology platforms and the related talent is also a major achievement under the alliance with Roivant. The two platforms taken over by us are DrugOme, which accelerates pipeline acquisition and

clinical development with unique data analysis, and Digital Innovation, which streamlines operations utilizing healthcare IT-related technology. I believe that these platforms and the talent related to them will enable us to further speed up digital transformation and contribute to the enhancement of business value of each department ranging from research and development through to sales at the Sumitomo Dainippon Pharma Group as a whole.

At present, we are also training staff in Japan to be in charge of solving business problems using DrugOme in individual departments, such as research and development. We also plan to assign around ten Digital Innovators in North America and a few of them in Japan to be responsible for Digital Innovation.



Dan Rothman, Chief Digital Officer (CDO) of the Sumitomo Dainippon Pharma Group

Technology Platforms

Utilization of DrugOme in Sumitomo Dainippon Pharma Group

Our Approach

Mid-term Business Plan 2022“Establishment of Growth Engine”

- Enhance Innovation Base with New Approaches to Drug Discovery
- **Drug discovery research with big data and digital technologies**
- Deliver Highest Performance of Clinical Development
- **Improvement in probability of success and efficiency with big data**



DrugOme

- Unique data analytics platform for accelerating clinical development and pipeline acquisition
- Computational Research team dedicated to DrugOme

Business Alliance with Roivant

- Healthcare data connectivity technology by Davant

Data-driven Pharmaceutical Company



Research

- Utilize real world data for in silico drug discovery (data-driven first in class drug discovery)

Development

- Optimize and improve clinical trials with big data analytics and integration
- Refine clinical development strategies
- Build evidence combining in-house (from clinical development to after launch) with real world data

Business Development

- Increase efficiency of in-licensing activities through unique data analysis (acquisition of promising assets)
- Refine valuation process with big data analytics and integration

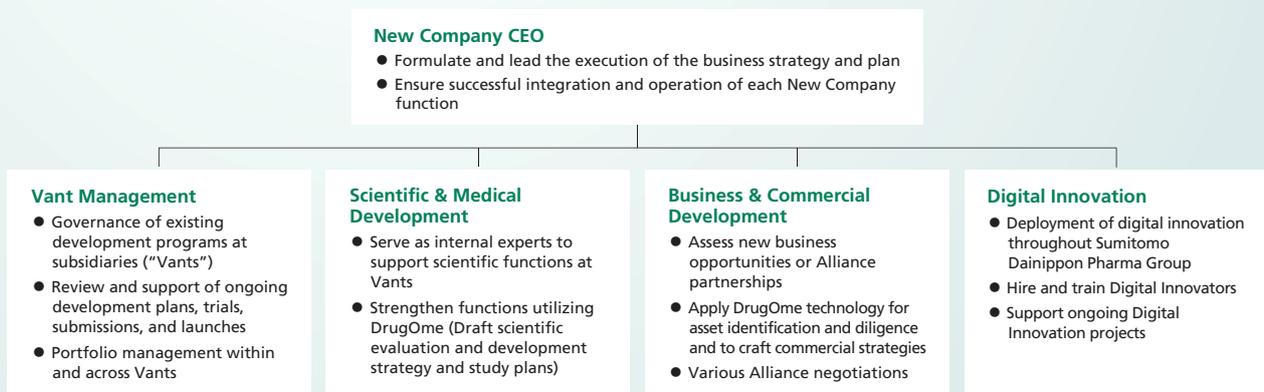
Q. How will you manage the five subsidiaries that have been acquired?

A. A new company established as a holding company will manage the five companies.

Sumitovant Biopharma, Inc. which was newly established as a holding company manages the five subsidiaries we acquired. We invited Myrtle Potter, who has served as President & COO at biotech company pioneer Genentech, to be CEO and lead the formulation and execution of business and sales strategy.

We recognize that the global expansion of the Sumitomo Dainippon Pharma Group has entered a new stage due to this strategic alliance. We will continue aiming to establish our position as a “Global Specialized Player” set out for 2033 through a transformation to a new pharmaceutical business model utilizing data and digital technology while evolving the Group’s management.

Management Structure of the New Company, Sumitovant Biopharma



Message from the CEO of Sumitovant

Our mission is to contribute to the development of even more outstanding and innovative pharmaceutical products and changing the lives of people around the world through initiatives that extensively utilize technology. We will become a growth engine for the Sumitomo Dainippon Pharma Group with contributions to expansion of the Group’s business regions and to its sustained business success. To achieve these goals, we will expand our pipeline to include not only the products in our portfolio but also acquisition of new candidate compounds for development with the aim of bringing pharmaceutical products to market more quickly.

While speeding up innovation, Sumitovant will also foster a corporate culture that values diversity & inclusion, respects the ideas of everyone, and enables all employees to have a sense of belonging.

Sumitovant has made a great start. I hope you are looking forward to our future.



Myrtle Potter
Chief Executive Officer

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.43](#)



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.
- 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.

[Details on p.43](#)



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.52](#)



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.
- We respond to inquiries on the quality, efficacy, and safety of our products from



M&A and Alliance

Sumitomo Dainippon Pharma is stepping up M&As and in-licensing and promoting alliances with outside research institutions from a viewpoint of expanding the development pipeline.

- We actively promote strategic investment in acquisitions and in-licensing.
- For in-licensing, we consider a wide range of assets in our focus areas with a priority on late-stage development assets and approved products.
- We enter into research alliances with research institutions, including universities in Japan and overseas, and biotech companies with innovative technologies.

[Contribution to Societies](#) [Details on p.61](#)

[Environment](#) [Details on p.64](#)

*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.53](#)



patients, their families, and healthcare professionals.

- We produce appropriate information materials, support the provision of information by medical representatives (MRs), and review externally-directed information and materials.

[Details on p.59](#)

- We engage in an open innovation activity called PRISM through which we call for original ideas and conduct joint research to match our drug discovery research needs.

[Details on p.51](#)

Innovation today, healthier tomorrows

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 healthcare 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.



Cashpoint We sell pharmaceutical products to wholesalers, delivering the products to medical institutions and health insurance pharmacies through wholesalers which are then prescribed to patients. The method for determining the official prices for ethical pharmaceuticals (drug prices) varies according to the country.



Research & Development

Basic policy

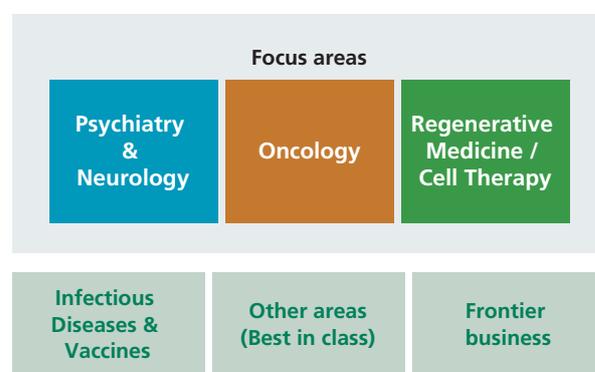
Concentrated investment in three focus research areas, promoting open innovation, and allocation of R&D investment by priority

In addition to R&D of excellent pharmaceutical products in three focus research areas (Psychiatry & Neurology, Oncology, and Regenerative Medicine/Cell Therapy), Sumitomo Dainippon Pharma engages in drug discovery in the infectious diseases & vaccines area and development of best in class pharmaceutical products focused on value for patients. We also aim to provide new healthcare solutions through the launch of frontier business in the non-pharmaceutical product area.

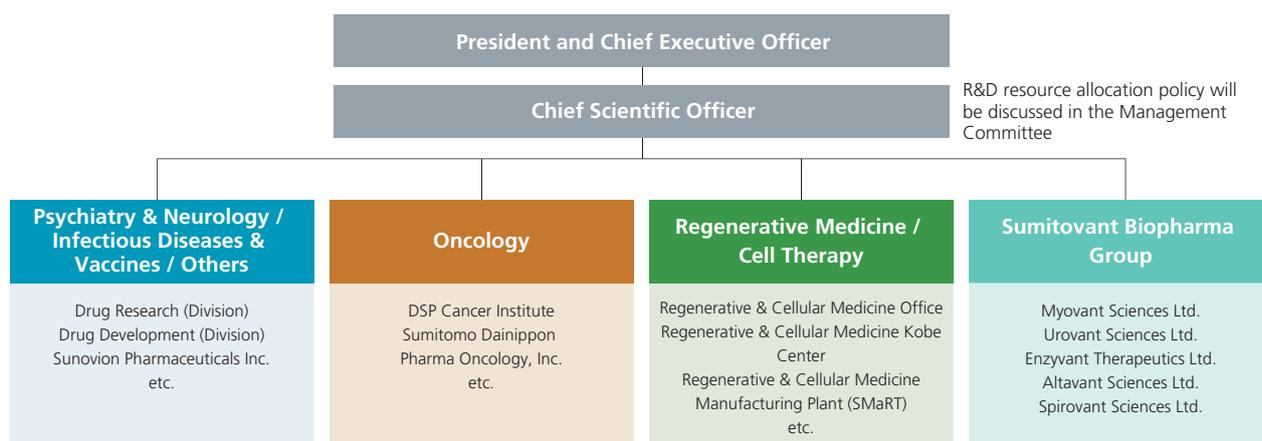
We are striving to enhance the innovation base with new approaches to drug discovery and deliver the highest performance of clinical development. Furthermore, we appointed a Chief Scientific Officer on April 1, 2020 to oversee R&D across all areas as well as to

provide integrated management of R&D resource allocation and achieve optimum R&D portfolio management.

Note: Please see “Strength: R&D” (p.25–28) for more details about the pipeline in each area and opportunities and risks.



Research & development system



Psychiatry & Neurology area

Mainly target psychiatric disorders with poor treatment satisfaction and neurodegenerative diseases aimed at disease modification as well as discovery of drugs for treating peripheral symptoms of neurodegenerative diseases.

Vision 2033

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

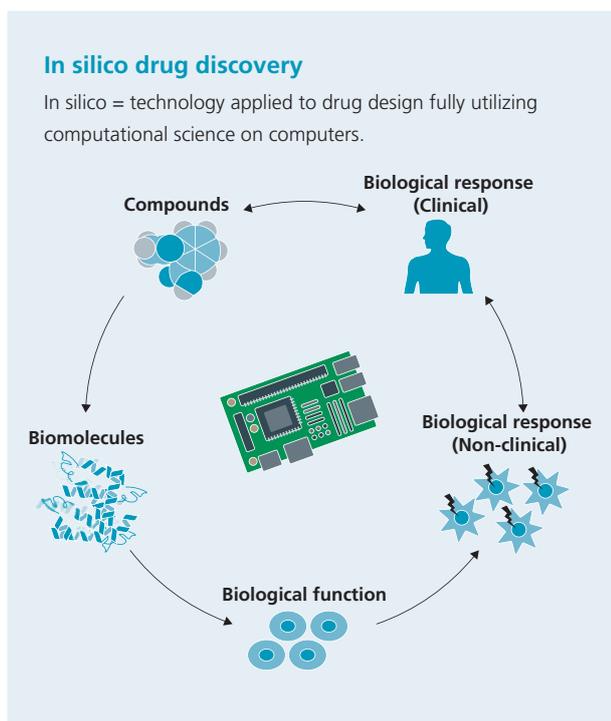
Sumitomo Dainippon Pharma has adopted as our R&D policy the achievement of precision medicine* through logical and rational pathophysiological-based drug discovery and providing total health care through combining pharmaceuticals with digital technologies. We also aim to overcome neurological diseases and move toward preventative medicine. We are implementing competitive drug discovery research based on our proprietary drug discovery platform incorporating cutting

edge technology. Knowledge obtained from clinical studies of products developed in-house is applied to translational research to select appropriate drug discovery targets or biomarkers based on big data such as genome information and imaging, thereby increasing the probability of success of R&D. In the area of psychiatric disorders, our goal is to optimize treatments through drug discovery based on neural circuit pathology. In the area of neurological disorders, our goal is radical treatments for neurodegenerative diseases through drug discovery based on molecular pathological mechanisms.

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.

*High precision medicine based on understanding of pathology and etiology through use of cutting-edge science and technology and patient stratification and prediction of treatment outcomes using biomarkers

Example of utilization of cutting-edge technology in Psychiatry & Neurology area



Optogenetics

Optogenetics, a technology to control specific neuronal activities using opto-stimulation in specific brain regions.

Functional neuroimaging

A technology for measuring physiological brain activity using electroencephalography and positron emission tomography (PET), etc. to elucidate the pathology of neuropsychiatric disorders and confirm the effect of drugs.

New modalities

In addition to conventional small molecule drugs and antibody drugs, modalities such as nucleic acid drugs and cell therapy are expected to offer new treatments for intractable diseases.

Drug discovery utilizing patient-derived iPS cells

A technology for confirming the safety and efficacy of drugs using disease-specific nerve cells differentiated from patient-derived iPS cells.

Research & Development

Direction of drug discovery

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

Drive genetics and neural circuit anomalies-based drug discovery for the treatment of schizophrenia, depression, psychiatric symptoms in neurological disorders, and developmental disorders.

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

Identify disease modifying drugs for dementia, Parkinson's disease, and rare diseases, maximizing the opportunities of advancements in science.

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.

Major products under development

(as of July 30, 2020)

SEP-363856*1

SEP-363856 is a candidate compound for an antipsychotic agent with a novel mechanism of action – a TAAR1 (trace amine-associated receptor 1) agonist with serotonin 5-HT_{1A} agonist activity that doesn't bind to dopamine D₂ or serotonin 5-HT_{2A} receptors. Phase 2 study results in patients with schizophrenia support the broad efficacy of SEP-363856 in treating both positive and negative symptoms of schizophrenia, while demonstrating a safety profile with notable similarities to placebo for extrapyramidal symptoms, weight gain, lipid and glucose derangements, and prolactin elevation.

In May 2019, it received Breakthrough Therapy designation*2 from the U.S. Food and Drug Administration (FDA). The Phase 3 study commenced in the U.S. in the first quarter of fiscal 2019 with the aim of market launch during fiscal 2023. We plan to develop new indications with the intent to grow it into a blockbuster drug that goes beyond LATUDA® at its peak, including additional indications.

*1 Sunovion discovered SEP-363856 in collaboration with PsychoGenics using its in vivo phenotypic SmartCube® platform and associated artificial intelligence algorithms.

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

SEP-4199

SEP-4199 is a non-racemic ratio of amisulpride enantiomers. Sunovion discovered that the pharmacology of amisulpride is enantiomer-specific, and that increasing the ratio of R-amisulpride to S-amisulpride increases the potency for serotonin 5-HT₇ receptors relative to dopamine D₂ receptors. SEP-4199 was designed to increase levels of serotonin 5-HT₇ activity intended to enhance antidepressant efficacy and produce reduced levels of D₂ receptor occupancy appropriate for the treatment of bipolar depression.

Although SEP-4199 did not achieve the primary endpoints in the Phase 2 study for Bipolar I depression, it did demonstrate clinically significant improvement. We are currently conducting investigations aimed at the commencement of a Phase 3 study.

DSP-1181

DSP-1181 is a novel compound created by Sumitomo Dainippon Pharma using Exscientia's artificial intelligence (AI) technologies. In contrast to conventional serotonin 5-HT_{1A} receptor partial agonists (non-benzodiazepine anxiolytics), DSP-1181 has a potent full agonistic activity for serotonin 5-HT_{1A} receptors and is suggested to have a long half-life, and therefore it is expected that DSP-1181 may have strong efficacy over a long period of time. In obsessive compulsive disorder (OCD) model animals with manipulated OCD-related neural circuit, DSP-1181 is suggested to have an earlier onset of efficacy than a standard medication, a selective serotonin reuptake inhibitor (SSRI).

At present, DSP-1181 is at the Phase 1 study stage for OCD as the intended indication.

Fiscal 2020 Events/Targets

Completed events/targets as of July 2020:

- Apomorphine: Obtain approval for OFF episodes associated with Parkinson's disease in the U.S.
- SEP-363856: Determine new indication for development (global study). Start Phase 2/3 study for schizophrenia in Asia including Japan and China
- SEP-4199: Obtain results of Phase 2 study for Bipolar I depression

Oncology area

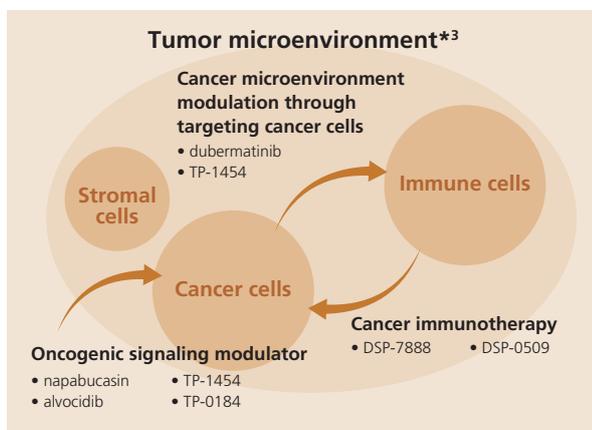
Build diversified and innovative development pipeline with research focused on tumor microenvironment (intercellular interaction or intracellular signaling)

Vision 2033

We will possess several global products and aim to establish a our group's oncology brand worldwide.

Through research focused on intra-cellular signaling and inter-cell networks in each cell population in the tumor microenvironment, we aim to discover innovative new drugs. Moreover, utilizing external collaboration, we will accelerate translational research and early clinical transition as well as drug discovery in step with the promotion of personalized medicine. In addition, we will strive for innovative technologies and promote drug discovery and development leveraging big data and digital technologies. We will also accelerate drug discovery through networks between Sumitomo Dainippon Pharma, its U.S. subsidiaries, and external institutions to boost the process, and obtain early approval.

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



*3 The microenvironment formed around a tumor in cancer tissue and surrounding host-derived cells, including stromal cells and immune cells, is related to tumor pathology, and significantly influences prognosis, sensitivity and resistance to treatment. Since the genetic abnormalities or signaling changes characteristic of cancer cells act on the development of the immune environment either directly or indirectly through changes in cytokine expression, efforts are also being made to improve the tumor microenvironment starting with its action on cancer cells.

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 select the optimum patient groups for each drug utilizing the appropriate biomarkers, accelerate POC*4 confirmation, and establish an oncology franchise.

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

Major products under development

(as of July 30, 2020)

Napabucasin (BBI608)

Napabucasin is an orally administered small molecule agent with a novel mechanism of action bioactivated by the enzyme NQO1 in cancer cells, which generates reactive oxygen species (ROS) to inhibit cancer stemness and tumor progression-related pathways including STAT3, which is expected to result in cancer cell death.

It is at the stage of the global Phase 3 study of combination therapy for colorectal cancer, and we aim to launch napabucasin during fiscal 2021 in the U.S. and during fiscal 2022 in Japan.

Alvocidib (DSP-2033)

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

We are conducting the Phase 1/2 study of combination therapy for myelodysplastic syndromes, and we aim to launch alvocidib during fiscal 2023 in the U.S.

Fiscal 2020 Events/Targets

Completed events/targets as of July 2020:

Napabucasin: Obtain results from the global Phase 3 study for colorectal cancer

Relugolix: Submit NDA for prostate cancer in the U.S.

Research & Development

Regenerative Medicine / Cell Therapy field

Pursue advanced manufacturing expertise and cutting-edge science to become a global leader

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.

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).



Regenerative Medicine and Cell Therapy Manufacturing Plant (SMaRT: Sumitomo Dainippon Manufacturing Plant for Regenerative Medicine & Cell Therapy)

Comprising two aboveground levels with a total floor area of 2,915m², the Plant is the world's first facility dedicated to the commercial manufacture of regenerative medicine and cell therapy products derived from allogenic iPS cells. The Plant complies with the latest standards, including GCTP (Good Gene, Cellular, and Tissue-based Products Manufacturing Practice), a standard for manufacturing and quality management of regenerative medicine and cell therapy. In addition to manufacturing investigational agents, we plan to carry out commercial production after obtaining approval.

Major products under development (as of July 30, 2020)

RVT-802

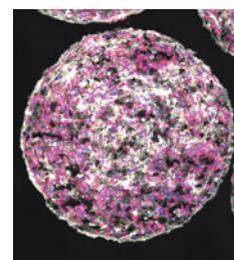
RVT-802, a one-time regenerative therapy, is cultured human thymus tissue engineered to generate a functioning immune response when implanted in pediatric patients with congenital athymia.

For patients who respond to RVT-802, a diverse T-cell population is established and thymic function sufficient to protect from infection usually develops between 6-12 months post treatment. In April 2019, we submitted an application to the FDA and received a Complete Response Letter (CRL) in December 2019. We plan to resubmit the application during fiscal 2020.

Parkinson's disease

In February 2017, allogenic 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 under the "SAKIGAKE Designation System" for regenerative medicine products by the Ministry of Health, Labour and Welfare.

Cell transplants have been completed for a total of three patients in an investigator-initiated clinical study through Kyoto University Hospital, and the intent is to complete a total of seven transplants during fiscal 2020. Based on the results of the clinical study, we are aiming to obtain the approval for the cells as a regenerative medicine product.



Dopaminergic neural progenitor cells (stained for specific markers)

Fiscal 2020 Events/Targets

Completed events/targets as of July 2020:

- RVT-802: Resubmit BLA for pediatric congenital athymia in the U.S.
- Allogenic iPS cell-derived products (AMD: age-related macular degeneration): Start clinical study
- Allogenic iPS cell-derived products (Parkinson's disease): Complete transplants in investigator-initiated clinical study

Infectious diseases & vaccines (AMR and adjuvanted vaccines)

Promote R&D in collaboration with academia aiming at contributing 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 products in the infectious diseases and vaccines area 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) CiCLE (Cyclic Innovation for Clinical Empowerment) program.

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 malaria vaccines with Ehime University, etc. and a universal influenza vaccination with the National Institutes of Biomedical Innovation, Health and Nutrition. We are also utilizing external funding with our malaria vaccine awarded from the Global Health Innovative Technology Fund (GHIT Fund) grant and our influenza vaccine selected for the Japan Agency for Medical Research and Development (AMED) CiCLE (Cyclical Innovation for Clinical Empowerment) program.

Fiscal 2020 Events/Targets

Completed events/targets as of July 2020:

- Antimicrobial resistance (AMR), universal influenza vaccine, malaria vaccine (transmission-blocking/blood-stage): Promote R&D projects

Other areas

We aim to develop best in class pharmaceutical products focused on value and pharmaceutical products in the diabetes area in Japan.

In addition to our own focus research areas, we promote pipeline acquisition through alliances and in-licensing and development in areas where we have a marketing base. Moreover, as is the case for relugolix and vibegron acquired through the strategic alliance with Roivant, we focus on the development of best in class new drugs which have clear advantages over existing drugs in the same class.

Major products under development (as of July 30, 2020)

Relugolix

Relugolix is a once-daily, oral gonadotropin-releasing hormone (GnRH) receptor antagonist that reduces testicular testosterone production, the hormone primarily responsible for stimulating prostate cancer, and ovarian estradiol production, hormones known to stimulate the growth of uterine fibroids and endometriosis. Myovant is developing relugolix as a monotherapy tablet for men with prostate cancer. Myovant is also developing a relugolix and hormone combination tablet for women with uterine fibroids and endometriosis.

New drug applications have been submitted to the FDA for the indications of prostate cancer and uterine fibroids with the aim of launching relugolix in the U.S. during fiscal 2020 for prostate cancer and during fiscal 2021 for uterine fibroids.

There have been positive results in two Phase 3 studies for endometriosis, and we plan to submit an application in the U.S. after we obtain the results of the extension study.

Vibegron

Vibegron is an oral, once-daily, small molecule β_3 adrenergic receptor agonist. Vibegron selectively acts on the β_3 adrenergic receptor in the bladder, relaxes the bladder, enhances urinary storage, and improves symptoms of urgency, urinary frequency, and urge urinary incontinence in overactive bladder.

A new drug application has been submitted to the FDA for the indication of overactive bladder with the aim of launching vibegron in the U.S. during fiscal 2020.

Research & Development

Imeglimin

Imeglimin, which was in-licensed from Poxel SA in October 2017, 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.

A new drug application has been submitted for the indication of type 2 diabetes with the aim of launching imeglimin in Japan during fiscal 2021.

Fiscal 2020 Events/Targets

Completed events/targets as of July 2020:

- Vibegron: Obtain approval for overactive bladder in the U.S. for Relugolix:
 - Obtain results from Phase 3 study for endometriosis (obtained results in April and June 2020)
 - Submit NDA for uterine fibroids in the U.S. (in May 2020)
 - Obtain approval for uterine fibroids in Europe
- Imeglimin: Submit NDA for type 2 diabetes in Japan (in July 2020)

Frontier business

Build a unique technology platform centering around our pharmaceutical business

Business Vision

We will build a business platform consisting of key technologies (including Information and Communication Technology 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.

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).

Main Projects

- Joint R&D with MELTIN MMI in medical devices utilizing bio-signal processing and robotics technologies.
- Collaboration with Sompo Japan Insurance Inc. and Aikomi Co., Ltd. for R&D and commercialization of digital devices for dementia and nursing care.
- Investment in Drawbridge Health, Inc., which is developing a blood collection device designed to enable simplified collection and transportation of dried blood samples for clinical lab testing.
- Joint development with Save Medical Co., Ltd. for mobile app for management of Type 2 diabetes.

Fiscal 2020 Events/Targets

Completed events/targets as of July 2020:

- Promotion of the current themes (MELTIN, Aikomi, Sompo Japan Insurance, Drawbridge, Save Medical, and internal themes), development of new themes

Intellectual property

Main Concept

As a pharmaceutical company, Sumitomo Dainippon Pharma considers the active management of intellectual property to be an essential part of its business strategy. Our basic policy is to develop our own robust intellectual portfolio, while at the same time respecting the intellectual property rights of others.

Comprehensive Approach to Intellectual Property—from Research Results to Business Development

We file patent applications covering inventions and products created at each laboratory to secure Sumitomo Dainippon Pharma's leading position. We also actively file patent applications covering inventions created in cooperation with outside research institutions. The Company currently has about 1,750 patents/patent applications. We especially focus on filing patent applications covering inventions created at the initial stage of research by cooperating with each laboratory and Intellectual Property Department to acquire effective patents and rights.

To comprehensively protect each of our products, we work to build a patent portfolio by not only applying for substance patents but also filing applications covering uses, manufacturing processes and formulations. In addition, we are working to establish intellectual property in the regenerative medicine/cell therapy field in order to promote the business. This approach ensures that our intellectual assets actively contribute to business development.

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

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) and the Declaration of Helsinki 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.

M&A and In-Licensing

Promoting M&As and In-Licensing

Sumitomo Dainippon Pharma actively promotes strategic investment in acquisitions and in-licensing from a viewpoint of expanding the development pipeline. For acquisitions, we evaluate huge volumes of information obtained in studies and referrals through our unique networks to develop concrete policy. For in-licensing, we consider a wide range of assets in our focus areas with a priority on late-stage development assets and approved products.

In fiscal 2019, through the strategic alliance with Roivant Sciences, we obtained multiple pipeline assets, including development assets expected to be approved by fiscal 2022 which could be near-term blockbuster products. In addition, we aim to be the Japanese market leader in the diabetes area, and concluded a Japan sales alliance agreement for Equa® and EquMet®, therapeutic agents for Type 2 diabetes.

Alliances with External Research Institutions

With the aim of continually creating new drugs, Sumitomo Dainippon Pharma enters into research alliances with research institutions, including universities in Japan and overseas, and biotech companies with innovative technologies. In fiscal 2019, we entered into an alliance in oncology research with three institutions in the U.S. – Columbia University, Harvard University and The Wistar Institute. Over a maximum of five years from September 2019, the group will have access to novel targets and platform technologies that may be discovered in the course of research projects supported by this alliance for the development of cancer drugs. We also entered into an agreement to invest in the MPM Oncology Innovations Fund, which focuses on investing in academia and growing early-stage companies that are developing new drug candidate compounds in the oncology area.

Furthermore, we engage in an open innovation activity called PRISM through which we call for original ideas from universities, research institutes, and corporations in Japan and conduct joint research to match our drug discovery research needs.

Major recent acquisitions and partnerships

Name	Date	Objectives	Consideration
Strategic agreement with Roivant Sciences Ltd.	December 2019	<ul style="list-style-type: none"> Acquisition of promising, future post-LATUDA compounds Acquisition of platform technologies and talent 	Approx. USD2.0 billion (not including acquisition of Roivant shares)
Acquisition of Tolero Pharmaceuticals, Inc. (currently Sumitomo Dainippon Pharma Oncology, Inc.)	January 2017	<ul style="list-style-type: none"> Acquisition of 6 compounds including CDK9 inhibitor, alvocidib Acquisition of outstanding expertise in drug discovery capabilities for kinase inhibitors and other drug targets 	USD200 million (not including development and marketing milestone payments)
Acquisition of Cynapsus Therapeutics Inc. (currently Sunovion CNS Development Canada ULC)	October 2016	<ul style="list-style-type: none"> Acquisition of KYNMOBI™ (APL-130277) : Bi-layer thin film developed with unique formulation technology for OFF episodes associated with Parkinson's disease 	Approx. USD635 million

Major recent in-licensing and co-promotion

Name	Date	Main details	Area
Novartis Pharma K.K. (Japan)	May 2019	Sales alliance in Japan for Equa® and EquMet®	Diabetes
Pfizer Japan Inc. (Japan)	March 2018	Co-promotion of EFFEXOR® in Japan	Psychiatry & neurology
Poxel SA (France)	October 2017	In-licensing of imeglimin in Japan, China, South Korea, Taiwan, and nine countries in Southeast Asia	Diabetes
Eli Lilly Japan K.K. (Japan)	July 2015	In-licensing of Trulicity® in Japan	Diabetes

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 made in fundamentally safe and sound operations.

We have made the Suzuka and Oita plants, our production sites in Japan, the foundation of our manufacturing to build a global supply chain that also 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 have realized a structure that can deliver products promptly to our pharmaceutical wholesalers all over Japan from our two distribution centers in Saitama and Kobe.

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 inspected and obtained the approval of overseas health authorities, including the FDA, the European Medicines Agency (EMA) and the Australia's Therapeutic Goods Administration (TGA), 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 International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH).

* 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 business activities in the areas of compliance, trustworthiness, 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 continuous operation 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 thorough compliance and precautionary measures.

Sales and Marketing

Japanese Market



Market Environment

Japan's ethical pharmaceuticals market is worth USD85.1 billion*1 (approximately 9 trillion yen), making it the world's third largest market behind the U.S. and China (as proportion of world market: 7.1%*1). Japan has universal health insurance, with pharmaceutical prices set by the Ministry of Health, Labour and Welfare. Pharmaceutical expenses are being curbed, and the use of generic drugs is recommended.

*1 Source: Prepared (All Rights Reserved) based on IQVIA World Review 2018, Copyright© 2020 IQVIA. Source: DATABOOK 2020, Japan Pharmaceutical Manufacturers Association (JPMA) (Conversion of values into yen calculated by Sumitomo Dainippon Pharma)

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

Brand Name	Therapeutic Indication	FY 2018	FY 2019	Rate of change (%)	FY 2020 forecast
Equa® / EquiMet®	Therapeutic agent for type 2 diabetes	—	17.1	—	40.5
Trulicity®*2	Therapeutic agent for type 2 diabetes	23.1	30.0	29.6	36.6
TRERIEF®	Therapeutic agent for Parkinson's disease	15.7	16.2	3.4	17.0
REPLAGAL®	Therapeutic agent for Fabry disease	12.5	13.3	6.3	13.3
METGLUCO®	Therapeutic agent for type 2 diabetes	10.1	9.6	(4.3)	8.8
LONASEN® Tape	Atypical antipsychotic	—	0.5	—	2.5
AmBisome®	Therapeutic agent for systemic fungal infection	4.0	4.2	3.6	4.0
LATUDA®	Atypical antipsychotic	—	—	—	2.2
AMLODIN®	Therapeutic agent for hypertension and angina pectoris	9.1	7.6	(16.2)	6.1
SUREPOST®	Therapeutic agent for type 2 diabetes	6.1	6.9	13.2	3.5

*2 Revenue of Trulicity® is shown by NHI price basis.

SWOT

Strengths

- Provision of neutral and detailed information based on extensive product lineup and top-class sales in Diabetes area.
- In-house product development capabilities and case-based treatment proposals taking advantage of dedicated CNS MRs in Psychiatry & Neurology area
- Implementation of digital innovation and effective e-promotion

Opportunities

- High unmet medical needs in Psychiatry & Neurology area
- Opportunities for in-licensing of other companies' product leveraging solid marketing base
- Increase in opportunities for healthcare professionals to obtain information digitally

Weaknesses

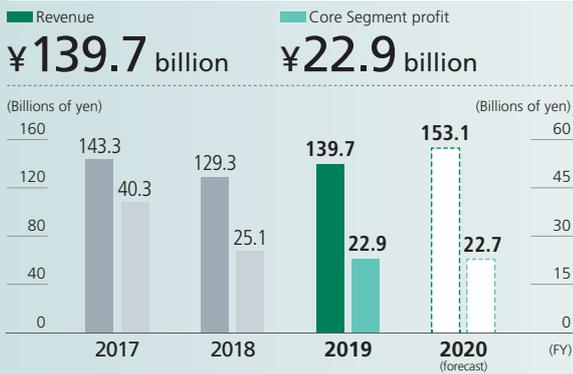
- Decline in profitability associated with changes in product mix

Threats

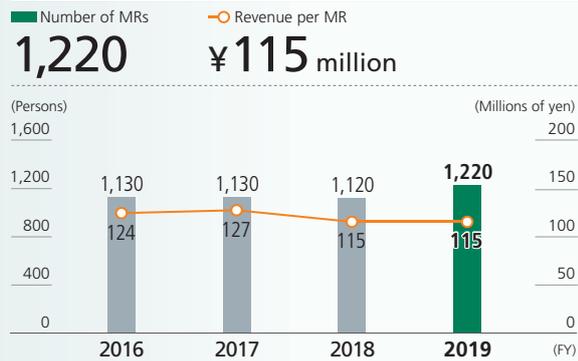
- Decline in revenue and profit associated with annual NHI price revisions
- Decline in revenue of long-listed products due to early penetration of generic drugs

*3 Number of MRs represents the number as of March 31 of the fiscal year
 *4 Revenue per MR in fiscal 2016 is calculated using net sales based on Japanese accounting standards.

Revenue / Core Segment profit



Number of MRs (Medical Representatives)*3 / Revenue per MR*4



Fiscal 2019 Main Initiatives and Business Results

Revenue increased by 8.1% year-on-year to reach 139.7 billion yen. Sales of products such as Trulicity® and SUREPOST® experienced a high rate of growth, and Equa® and EquMet® which the company started selling in November also contributed to the increase in sales. On the other hand, in addition to the impact due to NHI price revisions, sales of long-listed products declined.

Core segment profit decreased by 8.8% year-on-year to 22.9 billion yen despite the growth in revenue, as a result of changes in the product mix, including the growth of tie-up products and decline of long-listed products.

Fiscal 2020 Business Plan and Outlook

In the Psychiatry & Neurology area, we will aim to be the leading pharmaceutical company through the provision of high quality information by dedicated CNS MRs regarding LATUDA® launched in June 2020 and LONASEN® tape on which the prescription limitation will be lifted in October.

In the Diabetes area, we will fulfill our responsibility as the leading pharmaceutical company in Japan by providing the high-quality neutral information that is possible because we handle multiple therapeutic agents for diabetes with different mechanisms of action, such as Trulicity®, Equa®, and EquMet®.

Response to COVID-19

While there were regional variations, during the period when we voluntarily restricted our visit activities, we provided and collected information in accordance with customer circumstances by conducting interviews online utilizing IT tools in addition to providing information by e-mail. We also held briefings and lecture meetings online and began streaming video content based on the activities of dedicated remote MRs (iMR®) and virtual MRs (vMR™) utilizing original new characters.

We plan to continue utilizing IT tools to facilitate timely and appropriate provision and collection of information in addition to our conventional visit activities while assessing regional and customer circumstances.



Virtual MR (vMR™) characters

Sales and Marketing

North American Market



Market Environment

The U.S. market for ethical pharmaceuticals is worth USD484.5 billion*1 (approximately 50 trillion yen), making it the world’s largest market (as a proportion of world market: 40.4%*1), and it is one of the world’s most competitive markets.

As there is no universal public health insurance, the U.S. market is characterized by the extremely large presence of private health insurance. Moreover, based on the market principles in operation between pharmaceutical companies, insurance companies, and medical institutions, pharmaceutical companies can independently set drug prices.

*1 Source: Prepared (All Rights Reserved) based on IQVIA World Review 2018, Copyright© 2020 IQVIA. Source: DATABOOK 2020, Japan Pharmaceutical Manufacturers Association (JPMA) (Conversion of values into yen calculated by Sumitomo Dainippon Pharma)

Revenue of major products (Billions of yen)

Brand Name	Therapeutic Indication	FY 2018	FY 2019	Rate of change (%)	FY 2020 forecast
LATUDA®	Atypical antipsychotic	184.5	189.5	2.7	187.9
BROVANA®	Therapeutic agent for COPD	33.7	34.5	2.3	29.7
APTOM®	Antiepileptic	20.5	23.4	14.1	23.3
LONHALA® MAGNAIR®	Therapeutic agent for COPD	1.4	2.9	105.0	3.0
XOPENEX®	Therapeutic agent for asthma	4.6	4.1	(10.3)	4.6
KYNMOBI™	Therapeutic agent for Parkinson’s Disease OFF episodes	—	—	—	1.1

SWOT

Strengths

- Development and sales capabilities in the Psychiatry & Neurology area
- Late-stage best in class development assets focused on value and talent to lead development of these assets

Opportunities

- Enhancement of innovation base and digital transformation through technology platforms, DrugOme and Digital Innovation

Weaknesses

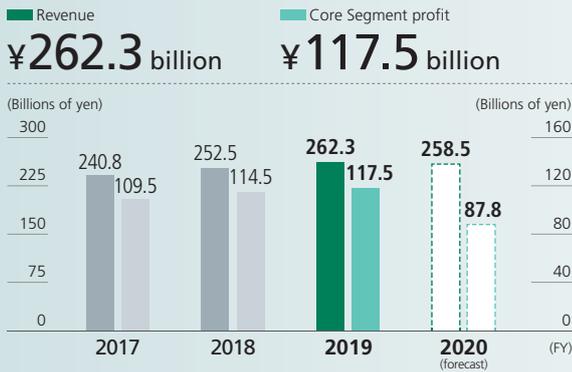
- Development of large-scale products to follow LATUDA® is an issue for future growth

Threats

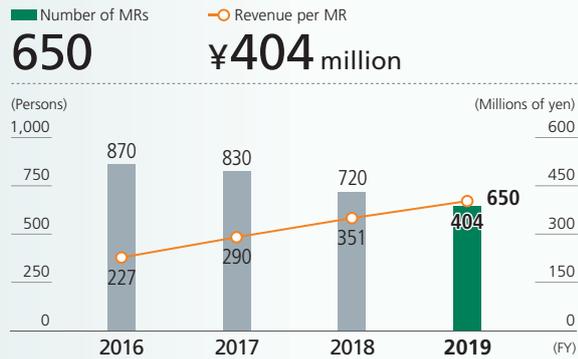
- Decline in profitability due to expiry of exclusive marketing period for LATUDA®

*2 Number of MRs represents the number as of March 31 of the fiscal year
 *3 Revenue per MR in fiscal 2016 is calculated using net sales based on Japanese accounting standards.

Revenue / Core Segment profit



Number of MRs (Medical Representatives)*2 / Revenue per MR*3



Fiscal 2019 Main Initiatives and Business Results

Revenue increased by 3.9% year-on-year to reach 262.3 billion yen. Sales of LATUDA® and APTIOM® increased steadily, contributing to revenue growth. Core segment profit increased by 2.6% year-on-year to reach 117.5 billion yen as revenue growth offset costs at Sumitovant and an increased acquisition-related expenses.

Fiscal 2020 Business Plan and Outlook

Going forward, it is expected that revenue of our products, including LATUDA®, will decline due to the impact of the COVID-19 pandemic, such as an increase in the unemployment rate in North America.

Core segment profit is also expected to decrease with a significant increase in sales-related expenses for new products in addition to the recording of full-year SG&A expenses for Sumitovant.

Response to COVID-19

As visits to medical institutions were restricted and direct interviews were often not possible, we implemented detailing activities utilizing an online interview system, an online Peer to Peer program (lectures), and online briefings.

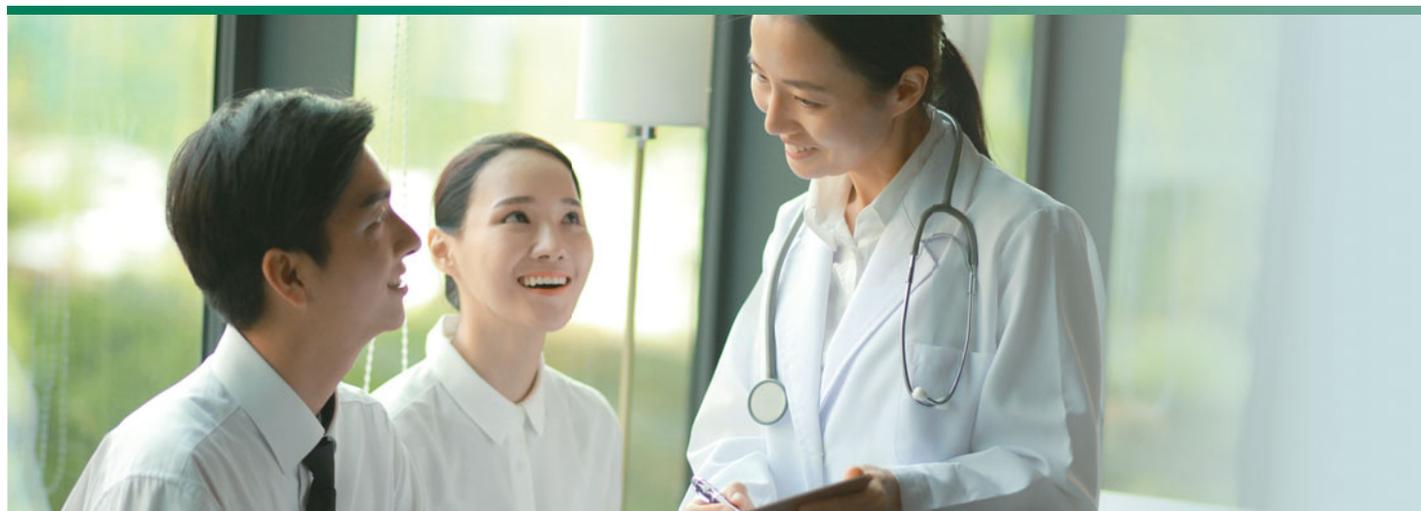
Although many medical institutions are maintaining the prohibition on visits as of July 31, 2020, we have resumed direct visits by MRs in 35 states which passed pre-established criteria.



Sales reps working from home conducts virtual meeting with HCP's office to convey product information

Sales and Marketing

Chinese and Asian Market



Market Environment

The Chinese ethical pharmaceuticals market is worth USD133.7 billion*1 (approximately 15 trillion yen), making it the world’s second largest market behind the U.S. (as proportion of world market: 11.2%*1). Although the growth rate has slowed due to policies to curb healthcare expenses, future growth is expected due to the aging population and rising income levels that come with economic development.

The ethical pharmaceuticals market for new drugs in Southeast Asia has experienced a high rate of growth to date. Continued growth is forecast going forward.

*1 Source: Prepared (All Rights Reserved) based on IQVIA World Review 2018, Copyright© 2020 IQVIA. Source: DATABOOK 2020, Japan Pharmaceutical Manufacturers Association (JPMA) (Conversion of values into yen calculated by Sumitomo Dainippon Pharma)

Region Covered

China and the six ASEAN countries (Thailand, Malaysia, the Philippines, Vietnam, Singapore, and Indonesia)

Products Sold

• China market

MEROPEN®, ALMARL®, Sediel®, GASMOTIN®, LONASEN®, LATUDA®

• East Asia and Southeast Asia market, ex China

MEROPEN®, LATUDA®

SWOT

Strengths

- Solid marketing base centered on Chinese subsidiary
- High quality, competitive in-house products, including MEROPEN®

Opportunities

- Policies to accelerate new drug approval have been developed, such as acceptance of overseas clinical data
- Continued growth is forecast going forward due to economic growth, improvement in healthcare infrastructure and others

Weaknesses

- Expansion of product lineup is an issue for future growth

Threats

- Implementation of policies to curb pharmaceutical expenses in countries with drug price systems based on public insurance

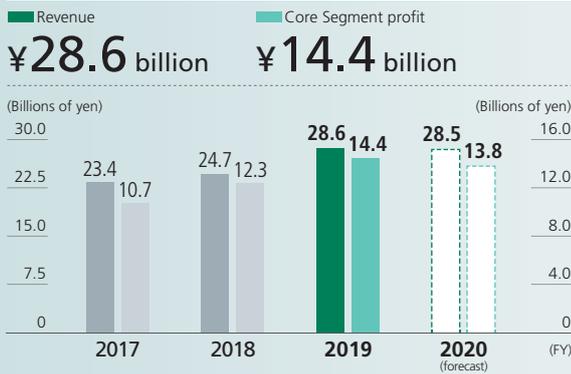
Revenue of Major Products (Billions of yen)

Brand Name	Therapeutic Indication	FY 2018	FY 2019	Rate of change (%)	FY 2020 forecast
MEROPEN®	Carbapenem antibiotic	21.2	24.1	13.2	23.0

Note: For China segment only

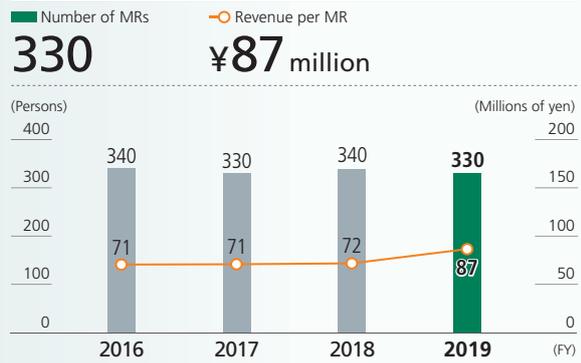
*2 Number of MRs represents the number as of March 31 of the fiscal year
 *3 Revenue per MR in fiscal 2016 is calculated using net sales based on Japanese accounting standards.

Revenue / Core Segment profit



Note: For China segment only

Number of MRs (Medical Representatives)*2 / Revenue per MR*3



Note: For China segment only

Fiscal 2019 Main Initiatives and Business Results

Revenue increased 15.6% year-on-year to reach 28.6 billion yen. This increase is attributable to an increase in sales of mainstay MEROPEN® and other products. Core segment profit increased by 17.2% year-on-year to reach 14.4 billion yen.

In the East Asia and Southeast Asia market, excluding China, led by our subsidiaries in Singapore and Thailand, we worked to maximize value of MEROPEN® and LATUDA® and strengthen the base in each country.

Fiscal 2020 Business Plan and Outlook

Sales of MEROPEN® in the China market in the first quarter of fiscal 2020 underperformed due to the impact of the COVID-19 pandemic. Segment profit is forecast to decline with revenue flat year-on-year and an increase in SG&A expenses.

In the East Asia and Southeast Asia market, excluding China, we will continue aiming to maximize the value of LATUDA® and MEROPEN® and for early submission for approval of development assets. We will also work to strengthen the business base through the transfer of sales approval and the establishment of a new subsidiary with the intention of sustained growth.

Response to COVID-19

In the Chinese market, we actively implemented online academic conferences and customer interviews in parallel with face-to-face information provision in order to make up for restrictions on face-to-face activities due to the impact of COVID-19.

In the East Asia and Southeast Asia market, excluding China, we held online product briefings and study meetings due to the impact of COVID-19. Going forward, we will continue looking into the roll out of online promotion and so forth utilizing digital tools.



Healthcare professionals attending an online study meeting (China)

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 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/management/policy.html>

Efficient inquiry-response 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, verifying manufacturing records and confirming 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 Pharmacovigilance, 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 tablets that have answers to frequently asked 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).

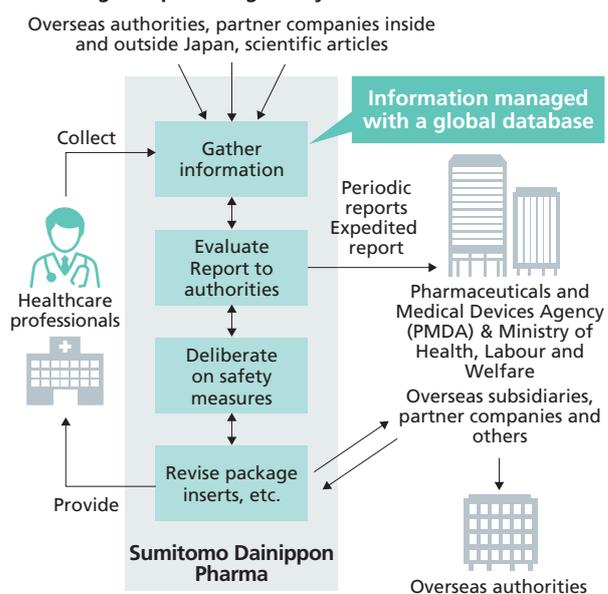
Centralized management of safety information from development to post-marketing

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 collected from 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, MRs carry tablets equipped with information on adverse reactions, including symptoms that need to be noted for early detection, types of patients likely to develop symptoms, and approaches to handle such occurrences, so that MRs can accurately communicate information to healthcare professionals in order to minimize the risks for patients.

**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 forms, and additional indications. MSL also serves as a contact person for clinical research and provides medical information based on advanced scientific knowledge in response to requests from healthcare professionals.

Promoting the provision of accurate product information based on scientific evidence

For providing accurate information to healthcare professionals, we create appropriate information on our products, support MRs’ provision of information, and conduct medical review

of information and materials for external use.

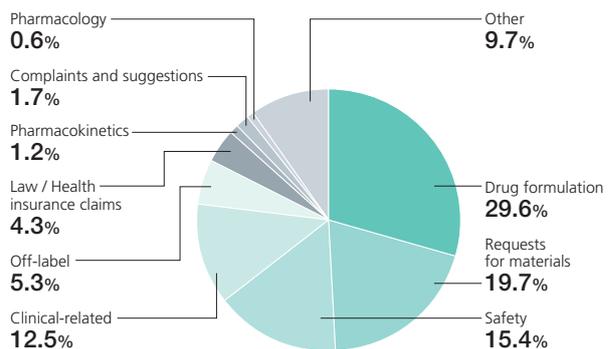
We also provide documents such as “Kusuri-no-shiori”, drug information sheet, and “Instructional Leaflets” which are used by healthcare professionals in explaining to patients. In order to be able to offer 24-hour support for regional healthcare, we will utilize our website and other methods, and continue to deliver and communicate easy-to-understand information to patients and families, while addressing the on-site needs of medical institutions.



**Act as an information hub
Further utilizing customer feedback**

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, visualizing trends in patient opinions, and strengthening our role to improve our products and materials.

Inquiries during FY2019: Approximately 36,900



Contribution to Societies

Contributing to global health and improving access to medicines

In recent years, expectations for 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.



Home visit by a maternal and child health volunteer (Cambodia)

Related SDGs



Main initiatives in FY2019

Vaccine development

The preclinical development project for a new malaria transmission-blocking vaccine (TBV), which Ehime University and Sumitomo Dainippon Pharma are jointly conducting with PATH of the United States was awarded a grant from the Global Health Innovative Technology Fund (the “GHIT Fund”). Success in this project will promote development aimed at a pioneering malaria TBV. We also concluded an agreement with the National Institutes of Biomedical Innovation, Health and Nutrition for joint research aiming at the practical application of an influenza vaccine that provides broader protection against influenza viruses. We aim to create a highly innovative next-generation vaccine that protects against various subtypes of influenza including not only seasonal but also pandemic influenza.

Participation in Access Accelerated

The Access Accelerated partnership initiative by organizations around the world, including global pharmaceutical companies, City Cancer Challenge, and PATH, launched Phase 2 for 2020 – 2022 to follow Phase 1 for 2017 – 2019. Sumitomo Dainippon Pharma has participated since the launch of Access Accelerated in 2017. Together with governments and local NGOs in the focus countries (Kenya, Ghana, and Vietnam), we are working for public education and pharmaceutical deregulation in disease areas with high local needs (non-communicable diseases such as cancer, heart disease, and diabetes) aiming for further strategic improvements in access to pharmaceuticals.

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. The following activities were conducted in fiscal 2019.

- Trained 55 Community Care volunteers for Mothers and New-borns (CCMN)
- Visited the homes of 350 antenatal women and 298 postnatal women
- Held practical cooking workshop for preparing highly nutritious baby food five times with participation by 124 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 several medical facilities in 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 to select the best antibiotics for treatment in each medical institution.

Initiatives for unapproved and off-label drugs

As an initiative to provide new treatment options in areas with high unmet medical needs, Sumitomo Dainippon Pharma puts an emphasis on responding to requests for development of unapproved and off-label drugs. 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. In addition to providing “Kusuri-no-shiori,” “Instructional Leaflets,” and guidance for patients using our pharmaceuticals and their families to promote appropriate use, we strive to educate the public through our health information site and by holding public lectures (24 lectures in fiscal 2019).

Patient support and advocacy

Support through donations

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

As we focus on support for patients and their families, global health, and educating the next generation, voluntary financial contributions by our officers and employees are matched by a corresponding Sumitomo Dainippon Pharma donation and presented to organizations that promote such causes.

Main donations in fiscal 2019

Matching donations

- The Support Network for NANBYO Children of Japan
- Future Code
- Nobel
- Florence
- Ashinaga

Global health

- Malaria No More Japan
- People’s Hope Japan

Biodiversity

- Keidanren Committee on Nature Conservation

Art

- Osaka Prefecture (Welfare office for persons with disabilities, Welfare department)

Contribution to local communities

- Osaka Voluntary Action Center

Supports of educating the next generation

- Japan Institute for Drug Education

Other

- Next Vision
- Japan Hearing Dogs for Deaf People

Patient advocacy

- Japan Patients Association
- Japan Fabry Disease Patients and Family Association
- Japan Epilepsy Association
- Japan Parkinson’s Disease Association
- Children’s Cancer Association of Japan

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 2019, JERF provided 12 research grants, two overseas study grants, and three Japan Epilepsy Research Grants for Inviting Overseas Researchers to Japan.

Advancing patient advocacy in the U.S.

During fiscal 2019, our U.S. subsidiary Sunovion Pharmaceuticals Inc. continued to support the National Alliance on Mental Illness (NAMI) walks, while also expanding the Be Vocal partnership between six leading mental health advocacy organizations and Sunovion. Be Vocal is designed to empower people living with mental health conditions to speak up when talking with their support team and to encourage everyone to speak up as a community to advance mental health in America. 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



Sunovion employees taking part in The Parkinson’s Unity Day Walk in the U.S.

Contribution to Societies

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 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 2019, participating students numbered approximately 1,800 at 25 schools, with 43 of our employees serving as instructors. We plan to launch a new program using the theme of genome analysis in the autumn of fiscal 2020.

We also host visits by junior high school students who have applied to learn about Sumitomo Dainippon Pharma's initiatives on the SDGs, introducing them to our goal of contributing to achieving the targets of the SDGs through the practice of our Corporate Philosophy as well as the creation of medicines, which is our business.

These initiatives stimulate the interest of children in science, and we believe that in addition to enhancing the quality of local community education, they also increase trust in our company and pave the way to obtaining the outstanding human resources of the future.

No. of employees teaching courses in visiting lectures

43

Schools using our visiting lectures / No. of attendees

25 schools/
1,800 attendees

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 and their families. 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 such as the action of medicines and the process for the creation of 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 fiscal 2019, we newly added "Gekkan Karada Column," which introduces topics related to the body and health that are related to the daily lives of junior high school students. We will continue providing columns that help to maintain and improve the health of junior high school students and counter poor physical health.

Related SDGs



SUKOYAKA Compass (Only available in Japanese)
<https://www.ds-pharma.co.jp/sukoyaka/>

Scoppi, the navigator on SUKOYAKA Compass

Environment

Environmental management

Sumitomo Dainippon Pharma uses energy, water resources, and a variety of chemical substances for R&D and for manufacturing products. The shutdown of operations, administrative penalties, or damage to social trust due to the occurrence of a serious environmental problem or an increase in expenses for environmental protection due to responding to new environmental issues could have a serious impact on operating results. On the other hand, initiatives such as reducing energy costs and the recycling of waste into valuable resources as well as the creation of products that contribute to solving environmental issues are business opportunities that help to make a positive financial impact. Under our Basic Environmental Policies, Sumitomo Dainippon Pharma formulates a three-year Mid-term Environmental Plan and an Annual Implementation Plan. We evaluate initiatives at the Environmental and Safety Committee and respond appropriately to risks and opportunities, thereby leading to the enhancement of corporate value.

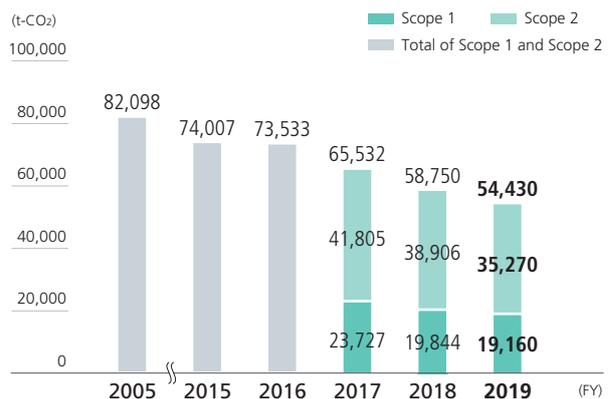
In fiscal 2019, we formulated new targets up to fiscal 2030 aimed at realizing a sustainable society.

- Reduce greenhouse gas (GHG) emissions (Scope 1 + 2) by 35% from fiscal 2017 level by fiscal 2030
- Reduce water withdrawal by 12% from fiscal 2018 level by fiscal 2030
- Maintain recycling rate for waste at 80% or higher and aim for at least 85%
- Maintain final disposal rate for waste at less than 1% and aim for less than 0.5%

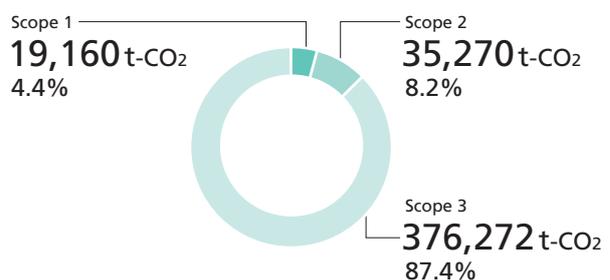
Contributing to building a low-carbon society

As part of our efforts to build a low-carbon society, which is one of our most important topics in the Mid-term Environmental Plan, we have set a target of reducing CO₂ emissions by 23% by fiscal 2020, compared to fiscal 2005. As of fiscal 2019, we had reduced emissions by 34%. 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, we are aiming to obtain Science Based Targets (SBT) certification for our fiscal 2030 GHG emission reduction target during fiscal 2020.

CO₂ emission trends



Fiscal 2019 CO₂ emissions by scope



Sumitomo Dainippon Pharma's environmental management



Environment

Identifying risks and opportunities

In light of the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD) and concerns about global water risk, we will analyze the identified risks and opportunities related to climate change and water. We conducted risk surveys on water risk, including water supply and demand (current and future) and vulnerabilities in downstream environments, at our main sites in fiscal 2019, which we will analyze going forward.

Third-party assurance

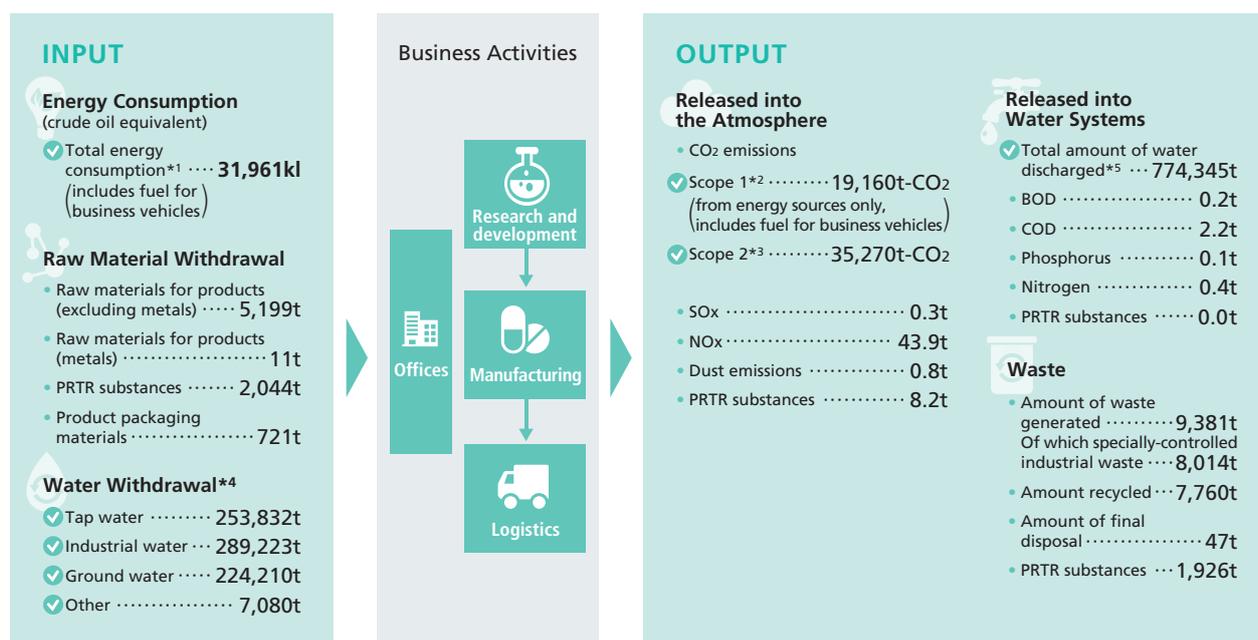
Fiscal 2019 environmental information indicated with a  in the Integrated Report 2020 has received third-party

assurance from KPMG AZSA Sustainability Co., Ltd. in order to enhance the reliability of the information. The Independent Assurance Report is on page 66.

Related SDGs



Overview of environmental impact (FY2019)



Boundary of calculation: Sumitomo Dainippon Pharma Co., Ltd. facilities in Japan only (plants, research laboratories, distribution centers, Osaka Head Office, Tokyo Head Office, branches and business offices). Water withdrawal, total amount of water discharged, and waste excludes 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 kJ/GJ
The unit calorific values and the types of fuel to be calculated are based on "Act on the Rational Use of Energy." However, 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.

*4 The amount of water withdrawal from tap water, industrial water, ground water, and other.

*5 Total amount of water discharged into sewerage and public water bodies and so on. As the amount of water discharged is not measured at each facility, the total amount of water discharged is considered to be equivalent to the total amount of water withdrawal.

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 performance indicators marked with  (the “Indicators”) for the period from April 1, 2019 to March 31, 2020 included in its Integrated Report 2020 (the “Report”) for the fiscal year ended March 31, 2020.

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.

Osaka, Japan

September 23, 2020

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.”

Corporate governance system

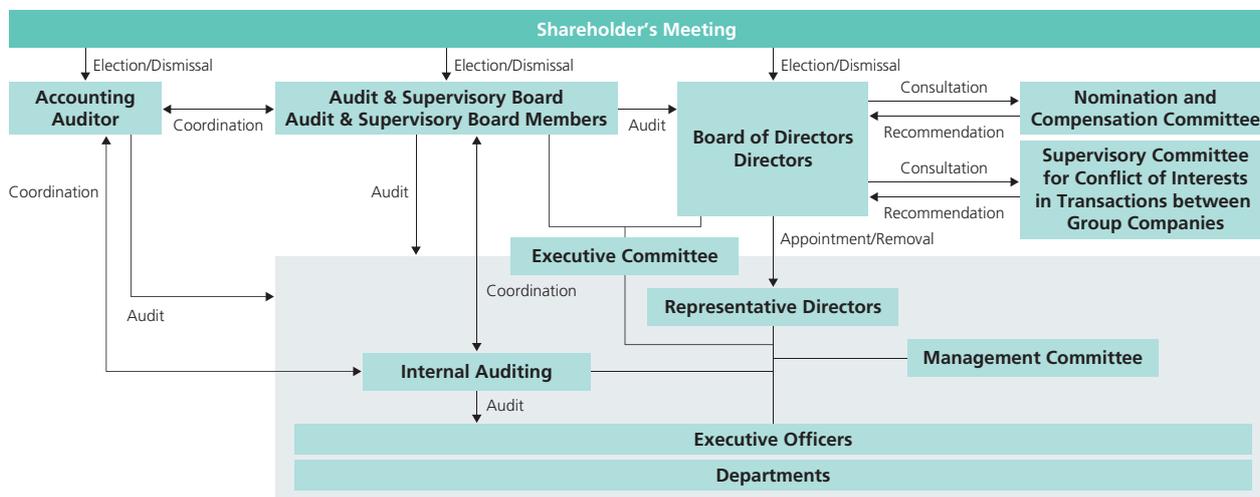
Sumitomo Dainippon Pharma has elected the organizational structure of a “Company with an Audit & Supervisory Board” to audit the execution of duties by the Directors, independent of the Board of Directors. In addition, the Company has adopted an executive officer system to

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 Company has set up the Supervisory Committee for Conflict of Interests in Transactions between Group Companies, which holds meetings as necessary, as a consultative body to the Board of Directors, and it consists of all the

Corporate governance structure



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 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.

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

Supervisory Committee for Conflict of Interests in Transactions between Group Companies

The Company has set up the Supervisory Committee for Conflict of Interests in Transactions between Group Companies (as of April 1, 2020) as a consultative body to the Board of Directors in order to ensure that the Company's significant transactions, etc. with its parent company or any subsidiary of the parent company (excluding the Company and its subsidiaries) are fair and reasonable and help protect the interest of minority shareholders of the Company. The meetings are held as necessary. The Committee consists of all the Independent Outside Directors, and the chairperson is appointed from among the members by mutual vote of the members.

Chairman	Saeko Arai (Outside Director)
Members	Yutaka Atomi (Outside Director) Nobuhiro Endo (Outside Director)

Independent Outside 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.

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 policies, audit plans, allocation of the duties 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

Accounting Audits, Remuneration (FY2019)

	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)	101
Total amount of fees to be paid in cash or otherwise by the Company or Subsidiaries of the Company	101

- 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.

Governance reform: progression of initiatives

(FY)

	2008–2012	2013	2014	2015	2016	2017	2018	2019	2020
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								
	Supervisory Committee for Conflict of Interests in Transactions between Group Companies								
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

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.

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 shall 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.

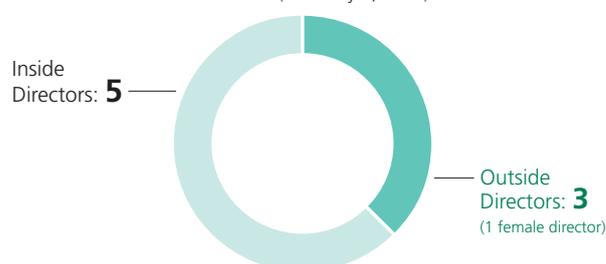
At present, three of the Outside Directors satisfy the

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.

The Independent Outside Directors participate actively in the Executive Committee and strive to understand the overall business of the Company. In light of this understanding, they make constructive statements at the meetings of the Board of Directors based on their respective expertise and extensive experience and broad perspective as corporate executives.

Ratio of Outside Directors (as of July 1, 2020)



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 Yoshiharu Ikeda	●					●	●	●
	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 (FY2019)

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 Met 20 times in fiscal 2019
The Audit & Supervisory Board	The Audit & Supervisory Board 5 members, (including three outside Audit & Supervisory Board members)	Once a month as a rule	Discussing and resolving important audit-related matters Met 13 times in fiscal 2019
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 2019
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 30 times in fiscal 2019
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 2019

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 (FY2019)

Category	Name	Name Principal Activities	Attendance/Frequency of Convocation (Attendance Rate)
Outside Director	Yutaka Atomi	He attended all twenty (20) meetings held by the Board of Directors during the fiscal year under review. He made statements at those meetings, primarily from the professional standpoint of a medical doctor.	20 times/20 times (100%)
	Saeko Arai	Out of the twenty (20) meetings during the fiscal year under review, she attended nineteen (19) meetings held by the Board of Directors. She made statements at those meetings, primarily based on her extensive experience as a corporate executive and from the professional standpoint of a certified public accountant.	19 times/20 times (95%)
	Nobuhiro Endo	He attended fifteen (15) of the sixteen (16) meetings held following his appointment as a Director. He made statements at those meetings, primarily based on his extensive experience and broad perspective as a corporate executive.	15 times/16 times (93%)
Outside Audit & Supervisory Board Members	Kazuto Nishikawa	He attended all twenty (20) meetings held by the Board of Directors and all thirteen (13) meetings held by the Audit & Supervisory Board during the fiscal year under review, and he made statements at those meetings, primarily from the professional standpoint of an expert in the fields of finance and accounting.	Board of Directors 20 times/20 times (100%) Audit & Supervisory Board 13 times/13 times (100%)
	Junsuke Fujii	He attended all twenty (20) meetings held by the Board of Directors and twelve (12) of the thirteen (13) 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 20 times/20 times (100%) Audit & Supervisory Board 12 times/13 times (92%)
	Yoshio Iteya	He attended nineteen (19) of the twenty (20) meetings held by the Board of Directors and all thirteen (13) meetings held by the Audit & Supervisory Board during the fiscal year under review. He made statements at those meetings, primarily from the professional standpoint of an attorney.	Board of Directors 19 times/20 times (95%) Audit & Supervisory Board 13 times/13 times (100%)

Messages from Outside Directors

In fiscal 2019, there were some extremely large projects, such as the strategic alliance with Roivant, and there were also diverse discussions at the Board of Directors. Looking back on the year, I feel that the Board of Directors was able to handle matters extremely efficiently due to its free and open discussion. In addition to the leadership of the Chairman and the President, I think that this is largely because the Company has ensured diversity of its Directors and Audit & Supervisory Board Members.

Drug discovery, which is the Company's business, comes with risks. Mechanisms and systems that ensure the delivery of risk information to senior management are important for conducting management with appropriate responses to risk. I believe we must verify and share our achievements and remaining issues thoroughly.



Yutaka Atomi

Fiscal 2019 saw the strategic alliance with Roivant, which was the Company's biggest investment ever. The strategic alliance contains opportunities and risks that will have a big impact on the Company going forward. The potential for creation of new drugs has expanded through the acquisition of a number of development assets that we expect to become major products in the future. However, should the acquired development assets not reach market launch or the strategic alliance not function, there is a risk that revenue and profit will slump. I also feel that the utilization of data will be the key that determines future business success.

The Board of Directors is having more vigorous discussions and becoming more effective every year. In addition to my specialist field, I intend to continue making recommendations with the perspective of patients and minority shareholders in mind going forward.



Saeko Arai

I feel that the content of the discussions at the Company's Board of Directors is extremely comprehensive and that governance is effective. As the management risks are broad in scope, I try to utilize my own knowledge as a manager in making recommendations at the Board of Directors.

At present, the Company is working on drug discovery using digital technology with the aim of long-term growth. Looking ahead to the future "new normal" era, I expect that pre-disease treatment known as pre-symptomatic measures will become important due to change in the concept of treatment. It can be said that this area is another field of digital medicine, including genes, and I think it is necessary for the Company to discuss what action it should take in such areas going forward.



Nobuhiro Endo

Audit & Supervisory Board Members

In accordance with the audit policies, audit plans, allocation of duties among members and other relevant matters determined by the Audit & Supervisory Board, each member strives to enhance the effectiveness of audit practices by holding meetings with the Representative Directors on a regular basis, proactively seeking reporting from the Directors and employees as necessary and having opportunities on a regular basis for collaboration with the Accounting Auditor and the Internal Auditing department,

and for collaboration in a three-party auditing structure. 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 audit the implementation status of the internal control system by such means as receiving reports from the Directors, employees and other relevant persons on the execution of their duties, requesting additional explanations as necessary, as well as conducting field audits at major offices and reviewing important approval

documents. The implementation status of the internal control system of subsidiaries of the Company is audited through field audits at overseas subsidiaries, holding meetings with the representative directors and other relevant persons of the subsidiaries located in Japan and abroad, holding meetings with audit & supervisory board members of the subsidiaries in Japan as necessary and seeking to obtain relevant information.

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 2019, the Nomination and Compensation Committee deliberated decisions on the compensation for the Directors and made recommendations to the Board of Directors. The Nomination and Compensation Committee also deliberated evaluation regarding the performance of the previous fiscal year and target setting for fiscal 2019 with respect to the performance-linked elements and individual performance. In addition, the Nomination and Compensation Committee deliberated the appropriateness of the level and composition of the compensation for the Directors, using sources such as survey data of outside specialized agencies. These deliberations were conducted four times in total in fiscal 2019.

(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. 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. Through such measures, the Directors' willingness to contribute to the increase of corporate value in the medium- to long-term is enhanced and value sharing with shareholders is promoted. The performance-linked compensation (bonuses) is calculated by the method described in (c) below, and the ratio of such compensation is approximately 10% of the total of compensation and the like.

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 by the Representative Director and President based on the standards deliberated at the Nomination and Compensation Committee, upon delegation of such decision to the Representative Director and President in accordance with the procedures described in the above (a) at a meeting of the Board of Directors. 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 multiplying performance-linked elements and individual performance, to the base amount which is set according to each position, such as Representative Director, and is determined to be within the scope of zero to 200% of the base amount.

The Group has set an original performance management indicator for its recurring profitability in the form of “core operating profit.” In FY2019, the performance-linked elements were evaluated by the Nomination and Compensation Committee based on the degree of achievement of targets, using this “core operating profit” as an indicator. As for the individual performance, the degree of achievement of performance targets of each Director was evaluated by the Nomination and Compensation Committee. The “core operating profit” forecast publicized in the announcement of the consolidated financial results for the previous fiscal year (77 billion yen) was used as a target, and the result was 72 billion yen.

Amount of executive remuneration (FY2019)

Category	Number	Amount of Remuneration (Millions of Yen)
Directors	10	378
Audit & Supervisory Board Members	5	87

- Notes: 1. The above includes the amount of remuneration and the like for Outside Directors and Outside Audit & Supervisory Board Members, seven persons in total, which is 72 million yen in total.
 2. The above includes two Directors who reached the end of their tenure at the conclusion of the 199th Ordinary General Meeting of Shareholders held on June 20, 2019, and one Director who reached the end of his tenure on March 31, 2020.
 3. The respective amounts of remuneration and the like for Directors and Audit & Supervisory Board Members that were determined in the 185th Ordinary General Meeting of Shareholders held on June 29, 2005 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 28 million yen in bonuses for Directors relating to fiscal 2019.

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. In fiscal 2018, the Company utilized external evaluation by outside legal counsel. In fiscal 2019, the Company evaluated the effectiveness of the Board of Directors after revising topics of the questionnaire.

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 on Corporate Governance 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 2019, the Company conducted a questionnaire on all the Directors and Audit & Supervisory Board Members during the period from February 2020 to March 2020. 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 and May of 2020.

2) Survey Categories

The major topics of the questionnaire for fiscal 2019 were as follows (topics 9), 10), and 11) were added this year):

- 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) Related party transactions
- 10) Strategic shareholdings
- 11) Training
- 12) Improvements from the previous fiscal year

3) Evaluation results

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 2019 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 and May of 2020. 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 2019 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 2018.

4) Major matters to be addressed in fiscal 2020

The following agendas have been identified as major matters to be addressed in fiscal 2020 as a result of the evaluation of the effectiveness of the Board of Directors for fiscal 2019.

- Enhancement of discussions for increasing corporate value in the medium- to long-term.
- Consideration regarding ideal members to constitute the Board of Directors for the future.
- Further improvement of the quality of deliberations by the Board of Directors.

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

Relationship with the parent company

Sumitomo Chemical Co., Ltd. is the parent company holding 51.78% (as of March 31, 2020) of the voting rights of the Company.

Sumitomo Dainippon Pharma's Basic Policy on Corporate Governance stipulates the objective of ensuring the Company's independence while respecting the management policy of the Sumitomo Chemical Group. When carrying out significant matters of business (mergers, capital increase/decrease, significant capital expenditure, investments and loans, etc.), we contact Sumitomo Chemical in advance. However, there are no restrictions by the parent company on our conduct of business activities (such as prior approval by the parent company), and a certain independence has been ensured.

In the case where the Company conducts significant 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. With respect to the Company's significant transactions, etc. with the parent Company's Group, deliberations are conducted from the viewpoint of protecting the interest of minority shareholders at the Supervisory Committee for Conflict of Interests in Transactions between Group Companies which was set up as a consultative body to the Board of Directors and consists of all the Independent Outside Directors.

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.

The Company expects to generate synergies in the regenerative medicine/cell therapy business in which the Company has engaged in research activities since the 1990s taking advantage of the large volume of useful knowledge and intellectual property possessed by Sumitomo Chemicals obtained through basic research using human ES cells in the area of regenerative medicine and joint research with RIKEN in the ophthalmology area. In addition, the functions of the Company's Genomic Science Laboratories were transferred to Sumitomo Chemical's newly established Bioscience Research Laboratory in January 2018. Through joint research with Sumitomo Chemicals taking full advantage of the functions of the Bioscience Laboratory, we are engaging in research activities that will include a broad range of perspectives on life science into the creation of pharmaceutical products as well as incorporating the healthcare business in addition to the pharmaceuticals business with the aim of fully utilizing synergies.

Management and governance of subsidiaries

With the aim of maximizing Group-wide corporate value, Sumitomo Dainippon Pharma has established corporate rules on operational management so that management of Group companies is conducted appropriately. We have set up departments to manage each Group company as well as departments that oversee this management, and we strive to understand the status of management and business execution at Group companies while providing the appropriate support for business execution.

Overseas in particular, we share our management mission and global strategy with Group companies while taking advantage of the strengths of acquired companies in their operations. Going forward, we will continue to strengthen group governance, aiming for sustained growth as a united group.

Strategic shareholdings

Sumitomo Dainippon Pharma shall not hold any shares of other companies except when such shareholding supports the sustainable enhancement of its corporate value, such as establishment or maintenance of corporate alliances and other types of relationships with important business

partners and customers. 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, 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 25 as of May 31, 2020.

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 proposals at a shareholders' meeting held for the first time after the occurrence of any major scandal 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 approximately three business 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 April 2019, Sumitomo Dainippon Pharma held a presentation on the Mid-term Business Plan 2022. In November 2019, we held an investors meeting presentation for the financial results at the end of the second quarter together with a presentation on the strategic alliance with Roivant as well as the second ESG meeting. In March 2020, we held an R&D 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 2019 held seven such meetings.

We also post other materials on our website in Japanese and English. These materials include financial results summaries and supplementary data, 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 notification system provided by the stock exchange, as well as on our website. 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

Based on the Companies Act, 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 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.

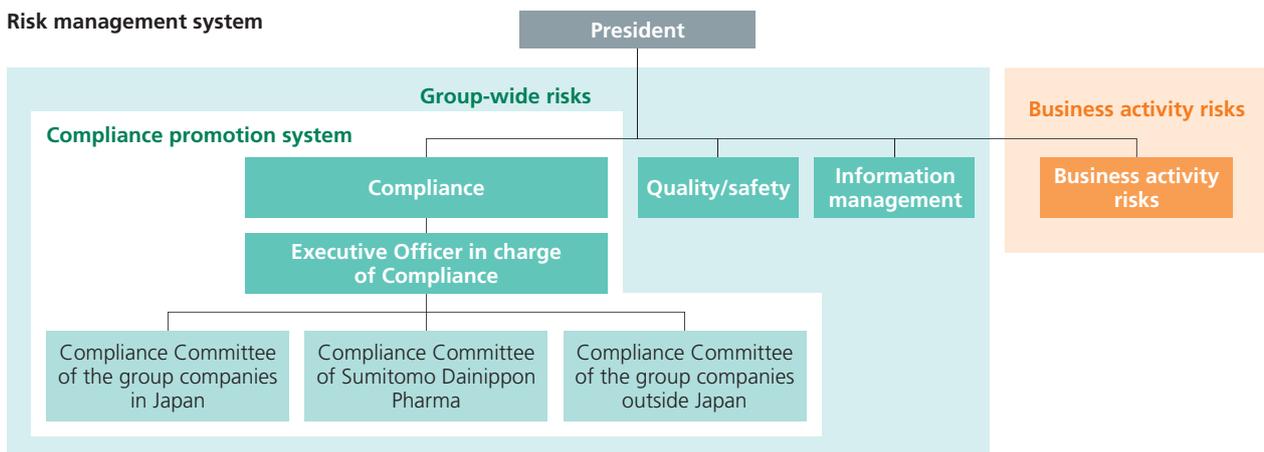
Risk management and compliance

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

Risk management system



with its guidance and advice as 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 for all business units, including Group companies in Japan and overseas, and formulate necessary countermeasures based on the results followed by implementation and evaluation. This is undertaken systematically by each business unit company-wide working on the solution to each problem.

In fiscal 2019, we ensured thorough management of research records using electronic lab notes to prevent loss of the reliability and reproducibility of experimental data through fabrication and alteration, as well as providing education for employees as a security measure against information leaks. We also organized a Crisis Management Team (CMT) for the purpose of promptly gathering helpful

Voluntary recall of METGLUCO® tablet 250mg/500mg

In April 2020, because N-nitrosodimethylamine (NDMA), which has been confirmed as carcinogenic, in several lots of METGLUCO® tablet 250mg/500mg blister packs was found to exceed the management indicator, we voluntarily recalled the lots of METGLUCO® tablet 250mg/500mg blister packs, in which NDMA exceeded or could exceed the management indicator from medical institutions. We are now shipping blister packs with a new design which does not contain the substance that forms NDMA.

In order to ensure that similar problems do not arise in METGLUCO® and other products that the Company manufactures and sells, we are striving to reduce quality risk and prevent recurrence by implementing quality management through a thorough system that includes continually ascertaining and monitoring that each production site and supplier carries out adequate quality management and production management based on appropriate management systems and providing the necessary guidance.

information needed to ensure accurate decision-making by the disaster response headquarters to be established in the event of a natural disaster, increasing our initial response capabilities for disasters.

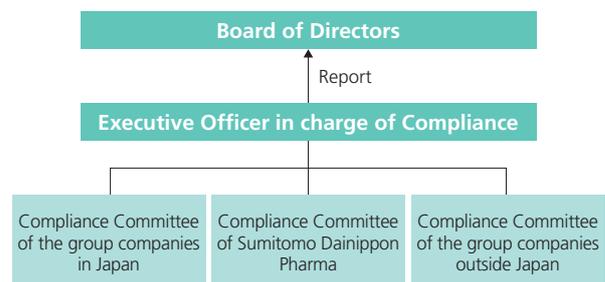
Compliance

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 2019, 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 installed in the group companies in and outside Japan. The officers and employees of such group companies may use the Sumitomo Dainippon Pharma hotlines, if the use of their own compliance hotlines is not appropriate.

Framework for compliance implementation



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. In fiscal 2019, CSIRT conducted response training based on a cyberattack scenario.

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 healthcare 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.

Guidelines for Provision of Sales Information on Prescription Drugs

In order to respond appropriately to the Guidelines for Provision of Sales Information on Prescription Drugs issued by the Ministry of Health, Labour and Welfare which commenced full-scale application on October 1, 2019, we established internal systems, including the Detailing Activities Supervision Department, the Review and Supervisory Committee chaired by an outside attorney, and a dedicated hotline for external complaints. The Detailing Activities Supervision Department also monitors detailing activities and reviews materials as well as providing education and training for officers and employees.

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, which 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.

Directors / Audit & Supervisory Board Members



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.
 2005: Senior Director of Personnel Development
 2008: Senior Director of Pharmaceutical Strategy
 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, Executive Director of Sales & Marketing Division
 2016: Member of the Board of Directors and Senior Executive Officer of the Company
 2018: In charge of the Sales & Marketing Division, 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
 2017: Senior Executive Research Director of Drug Research Division
 2019: Member of the Board of Directors and Senior Executive Officer of the Company (to the present)
 2020: Member of the Board of Directors and Chief Scientific Officer, in charge of Regenerative & Cellular Medicine Office, Regenerative & Cellular Medicine Kobe Center, Regenerative & Cellular Medicine Manufacturing Plant, and the Drug Research Division; and Senior Executive Research Director of the Drug Research Division of the Company (to the present)

5 Yoshiharu Ikeda

Member, Board of Directors, Senior Executive Officer

1985: Joined the former Sumitomo Pharmaceuticals Co., Ltd.
 2007: Senior Director of Research Planning & Coordination
 2009: Senior Director of Global Corporate Strategy
 2010: Executive Officer of the Company
 2012: Executive Vice President of Sunovion Pharmaceuticals, Inc.
 2013: Executive Officer, Executive Director of the Information Systems Planning Division and the Technology Research & Development Division
 2016: Senior Executive Officer, Executive Director of the Manufacturing Division and the Technology Research & Development Division
 2020: Member, Board of Directors and Senior Executive Officer; in charge of Regulatory Affairs, Medical Information, Medical Affairs, Corporate Regulatory Compliance & Quality Assurance Division, Technology Research & Development Division, and Manufacturing Division; Executive Director of Corporate Regulatory Compliance & Quality Assurance 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)
 2019: Outside Audit & Supervisory Board Member of Sanki Engineering Co., Ltd. (to the present)



Audit & Supervisory Board Members

7 Saeko Arai

Member, Board of Directors (Outside)

1987: Joined Eiwa Audit Corporation (currently, KPMG AZSA LLC)
 2002: Established Gratia, Inc. (currently, Acuray, Inc.) and assumed the position of President thereof (to the present)
 2017: Outside Audit & Supervisory Board Member of teamS Inc. (to the present)
 2017: Outside Audit & Supervisory Board Member of AEON Credit Service Co., Ltd. (to the present)
 2018: Outside Member of the Board of Directors of the Company (to the present)
 2018: Outside Member of the Board of Directors of Tokyu Fudosan Holdings Corporation (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)
 2019: Director and Chairman of the Board of NEC Corporation (to the present)
 Outside director of Tokio Marine Holdings, Inc. (to the present)

9 Yoshinori Oh-

Audit & Supervisory Board Member

1982: Joined the former Dainippon Pharmaceutical Co., Ltd.,
 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.
 2016: Outside Audit & Supervisory Board Member of The Royal Hotel, Limited
 2017: Outside Audit & Supervisory Board Member of the Company (to the present)
 2020: Outside Audit & Supervisory Board Member of House Foods Group Inc. (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



Hiroyuki Baba
Senior Executive Officer

Global Data Design Office; External Affairs; Legal Affairs; Intellectual Property; Corporate Secretariat; IT Management & Digital Transformation; Frontier Business Office

1982: Joined Sumitomo Chemical Co., Ltd.
2014: Joined the Company
Executive Officer,
Senior Director Global Business Development and Head of Global Business Development
2017: Legal Affairs; Intellectual Property; IT Management & Digital Transformation and Senior Director of Global Corporate Planning
2019: Senior Executive Officer
2020: Senior Executive Officer,
Global Data Design Office; External Affairs; Legal Affairs; Intellectual Property; Corporate Secretariat; IT Management & Digital Transformation; Frontier Business Office (to the present)



Shigeyuki Nishinaka
Senior Executive Officer

Global Corporate Strategy; Global Business Development; International Business Management

1989: Joined Nihon Kokan Co., Ltd. (currently, JFE Steel Corporation)
1994: Joined the former Sumitomo Pharmaceuticals Co., Ltd.
2001: Joined Daiichi Pharmaceutical Co., Ltd. (currently, Daiichi Sankyo Co., Ltd.)
2009: Joined the Company
2014: Deputy Executive Director of Drug Research Division and Senior Director of Global Oncology Office, Deputy Executive Director of Drug Research Division and Senior Director of External Innovation Development Office
2016: Senior Director of Global Business Development
2017: Executive Officer
2020: Senior Executive Officer,
Global Corporate Strategy; Global Business Development; International Business Management (to the present)



Hideyuki Harada
Executive Officer

Executive Research Director, Drug Research Division

1991: Joined the former Sumitomo Pharmaceuticals Co., Ltd.
2012: Senior Director of Research Planning & Coordination
2013: Senior Director of Research Planning & Intelligence
2016: Executive Officer,
Executive Director of Drug Research Division
2017: Executive Officer,
Executive Research Director of Drug Research Division (to the present)



Atsuko Higuchi
Executive Officer

Corporate Governance; Corporate Communications; Human Resources

1986: Joined Sumitomo Chemical Co., Ltd.
1992: Joined the former Sumitomo Pharmaceuticals Co., Ltd.
2008: Senior Director of Public Relations
2014: Senior Director of International Business Management
2017: Executive Officer,
Corporate Governance (External Communications); Personnel (Diversification)
2020: Executive Officer,
Corporate Governance; Corporate Communications; Human Resources (to the present)



Takuya Taguchi
Executive Officer

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

1982: Joined Sumitomo Chemical Co., Ltd.
1984: Joined the former Sumitomo Pharmaceuticals Co., Ltd.
2010: Senior Director of Higashi-Nippon Region Minami-Tohoku Branch
2012: Senior Director of Capital Region Tokyo Branch I
2013: Senior Director of Sales & Marketing Management
2019: Executive Officer,
Deputy Executive Director of Sales & Marketing Division; Senior Director of Sales & Marketing Management (to the present)



Shinichiro Katayanagi
Executive Officer

Chair and CEO, Sumitomo Dainippon Pharma America, Inc.

1982: Joined Nihon Cement Co., Ltd. (currently, Taiheyo Cement Corporation)
1991: Joined Yamanouchi Pharmaceutical Co., Ltd. (currently, Astellas Pharma Inc.)
2015: Joined Toho Holdings Co., Ltd.
2016: Joined the Company
2019: Executive Officer
2020: Executive Officer,
Chair and CEO, Sumitomo Dainippon Pharma America, Inc. (to the present)



Koichi Kozuki
Executive Officer

Drug Development Division
Executive Director, Drug Development division
Deputy Executive Director, Corporate Regulatory Compliance & Quality Assurance Division
Deputy Head of Japan Business Unit

1989: Joined the former Sumitomo Pharmaceuticals Co., Ltd.
2012: Senior Director of Global Project Management
2013: Senior Director of Global Strategy & Business Development
2014: Senior Director of Global Strategy & Business Development and Senior Director of Global R&D Office
2017: Executive Director of Drug Development division
2020: Executive Officer, Drug Development Division and Executive Director, Drug Development division, Deputy Executive Director, Corporate Regulatory Compliance & Quality Assurance Division, Deputy Head of Japan Business Unit (to the present)



Isao Shimizu
Executive Officer

Executive Research Director, Drug Research Division

1991: Joined
2014: Senior Director of Drug Development Research Laboratories
2016: Senior Director of Preclinical Research Laboratories
2017: Senior Director of External Innovation Development Office
2019: Senior Director of External Innovation
2020: Executive Officer, Executive Research Director of Drug Research Division (to the present)



Yumi Sato
Executive Officer

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

1992: Joined the former Sumitomo Pharmaceuticals Co., Ltd.
2015: Senior Director of Clinical Research
2018: Senior Director of Global Corporate Strategy
2020: Executive Officer, Executive Vice President and Chief Corporate Strategy Officer, Sunovion Pharmaceuticals Inc. (to the present)



Antony Loebel
Executive Officer

President and CEO, Sunovion Pharmaceuticals Inc.

2001: Joined Pfizer Inc.
2007: Joined Daiinippon Sumitomo Pharma America, Inc. (currently, Sunovion Pharmaceuticals Inc.)
2011: Chief Medical Officer, Sunovion Pharmaceuticals Inc.
2012: Executive Officer, Head of Global Clinical Development
2019: Executive Officer, President and CEO, Sunovion Pharmaceuticals Inc. (to the present)



Patricia S. Andrews
Executive Officer

CEO, Sumitomo Daiinippon Pharma Oncology, Inc.
Global Head of Oncology

1991: Joined Pfizer Inc.
2008: Joined Incyte Corporation
2013: Joined Boston Biomedical, Inc. (currently, Sumitomo Daiinippon Pharma Oncology, Inc.)
2017: Executive Officer, CEO, Boston Biomedical, Inc.
2020: Executive Officer, CEO, Sumitomo Daiinippon Pharma Oncology, Inc. Global Head of Oncology (to the present)

Ten-Year Summary of Selected Financial Data

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

Japanese GAAP	2011	2012	2013	2014	2015	2016
RESULTS OF OPERATIONS:						
Net sales	¥379,513	¥350,396	¥347,724	¥387,693	¥371,371	¥403,206
Overseas sales revenue	152,226	130,243	133,125	174,286	174,911	215,055
Ratio to net sales	40.1%	37.2%	38.3%	45.0%	47.1%	53.3%
Cost of sales	110,030	98,857	101,686	104,100	101,228	104,471
Selling, general and administrative expenses	238,531	231,137	220,994	241,450	246,868	261,805
(Research and development costs)	68,160	56,891	59,844	69,804	71,304	82,034
(Ratio to net sales)	18.0%	16.2%	17.2%	18.0%	19.2%	20.3%
Operating income	30,952	20,402	25,044	42,143	23,275	36,930
Operating margin	8.2%	5.8%	7.2%	10.9%	6.3%	9.2%
Net income attributable to owners of the parent	16,796	8,630	10,044	20,061	15,448	24,697
FINANCIAL POSITION:						
Total assets	¥589,868	¥559,410	¥607,219	¥659,033	¥711,584	¥707,717
Net assets	323,983	319,227	349,248	398,540	451,021	446,473
OTHER STATISTICS:						
Capital expenditures	¥8,663	¥ 8,742	¥ 12,384	¥ 23,421	¥ 10,676	¥9,785
Depreciation and amortization	44,628	40,232	35,085	26,777	19,226	20,267
PER SHARE OF COMMON STOCK:						
Basic net income	¥ 42.27	¥ 21.72	¥ 25.28	¥ 50.49	¥ 38.88	¥ 62.16
Net assets	815.44	803.47	879.03	1,003.11	1,135.21	1,123.76
Cash dividends applicable to the year	18.00	18.00	18.00	18.00	18.00	18.00
FINANCIAL INDICATORS:						
ROE	5.0%	2.7%	3.0%	5.4%	3.6%	5.5%
ROA	2.8%	1.5%	1.7%	3.2%	2.3%	3.5%
Equity ratio	54.9%	57.1%	57.5%	60.5%	63.4%	63.1%
Dividend payout ratio	42.6%	82.9%	71.2%	35.7%	46.3%	29.0%

Notes 1. 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.

2. 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.

3. 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.

4. ROIC: (Core operating profit – Income taxes) / (Capital + Interest-bearing liabilities)

Millions of yen

	2017	2018
	¥411,639	¥477,966
	227,495	290,321
	55.3%	60.7%
	100,071	119,852
	259,066	292,291
	80,819	91,397
	19.6%	19.1%
	52,501	65,823
	12.8%	13.8%
	28,733	37,525
	¥783,640	¥801,425
	460,389	483,050
	¥ 10,619	¥ 10,060
	18,649	19,909
	¥ 72.32	¥ 94.45
	1,158.80	1,215.84
	20.00	28.00
	6.3%	8.0%
	3.9%	4.7%
	58.8%	60.3%
	27.7%	29.6%

Millions of yen

IFRS	2017	2018	2019	2020
RESULTS OF OPERATIONS (Core Basis):				
Revenue	¥408,357	¥466,838	¥459,267	¥ 482,762
Overseas sales revenue	224,234	281,434	293,325	307,819
Ratio to revenue	54.9%	60.3%	63.9%	63.8%
Cost of sales	94,523	112,345	113,109	128,346
Selling, general and administrative expenses	171,385	186,176	186,143	189,979
Research and development expenses	81,373	86,881	82,891	92,607
Ratio of R&D expenses to revenue	19.9%	18.6%	18.0%	19.2%
Core operating profit	64,372	90,604	77,299	71,982
Ratio of core operating profit to revenue	15.8%	19.4%	16.8%	14.9%
Net profit attributable to owners of the parent	31,316	53,448	48,627	40,753
FINANCIAL POSITION:				
Total assets	¥779,072	¥809,684	¥834,717	¥1,252,878
Total equity	412,268	452,723	498,138	632,105
OTHER STATISTICS:				
Capital expenditures	¥ 7,835	¥ 10,184	13,231	¥ 11,982
Depreciation and amortization	12,713	12,887	13,976	17,365
PER SHARE OF COMMON STOCK:				
Basic net profit	¥ 78.82	¥ 134.53	¥ 122.39	¥ 102.58
Equity attributable to owners of the parent	1,037.68	1,139.50	1,253.82	1,332.72
Cash dividends applicable to the year	20.00	28.00	28.00	28.00
FINANCIAL INDICATORS:				
ROIC	11.5%	12.1%	11.8%	3.3%
ROE	7.8%	12.4%	10.2%	7.9%
ROA	4.2%	6.7%	5.9%	2.0%
Ratio of equity attributable to owners of the parent to total assets	52.9%	55.9%	59.7%	42.3%
Dividend payout ratio	25.4%	20.8%	22.9%	27.3%

Operating Results and Financial Condition, and Business Risks

Operating results and financial condition

Overview of overall operating results

During the fiscal year ended March 31, 2020, in the pharmaceutical sector, R&D expenses continue to rise, and competition is intensifying as governments take further steps to curb the prices of brand-name drugs and promote the use of generics. Meanwhile, there have been some moves to utilize digital technology for drug discovery and forge ahead with business in the areas of preventive medicine and presymptomatic diseases.

Against this backdrop, the Group has advanced business activity based on the Mid-Term Business Plan 2022 ("the MTBP"), which the Group published in April 2019, commencing in fiscal 2018 and running for five years to fiscal 2022.

In Japan, the Group has sought to bolster sales of mainstay products, such as Trulicity® and TRERIEF®, while at the same time focusing on the provision of medical information to maximize sales of Equa® and EquMet®.

In North America, Sunovion Pharmaceuticals Inc. (hereinafter, "Sunovion") continued to pour its resources into maximizing revenue of global strategic product LATUDA® and expanding sales of other mainstay products.

Following the signing of a definitive agreement for a strategic alliance with Roivant Sciences Ltd. (hereafter, "the Alliance") in October 2019 and the completion of the procedure related to stock transfers, etc. in December 2019, Sumitovant Biopharma Ltd. and the operating entities under this holding company, including Myovant Sciences Ltd., Urovant Sciences Ltd., Enzyvant Therapeutics Ltd., Altavant Sciences Ltd., and Spirovant Sciences Ltd., as well as their subsidiaries, have joined the Group.

Through the Alliance, the Company has acquired multiple pipelines, including relugolix and vibegron, both of which are blockbuster candidates that are expected to sustain growth after the expiration of the term for market exclusivity of LATUDA®. In addition, the Company acquired DrugOme and Digital Innovation, which should accelerate its digital transformation, as well as talents who run these healthcare technology platforms through the Alliance.

In the oncology area, the launch of napabucasin, which is under development by another U.S. subsidiary, Boston Biomedical, Inc., continues to be assumed top priority despite the discontinuation of its Phase 3 study in patients with pancreatic cancer; however, the Phase 3 study of the product for colorectal cancer is moving forward. Meanwhile, Tolero Pharmaceuticals, Inc. continued to focus on research and development of anti-cancer drugs (In July 2020, Boston Biomedical, Inc. and Tolero Pharmaceuticals, Inc. have integrated into Sumitomo Dainippon Pharma Oncology, Inc.)

In China, Sumitomo Pharmaceuticals (Suzhou) Co., Ltd.

pursued business opportunities in a bid to expand sales of MEROPEN®, LATUDA®, which was released there in September 2019, and other products.

Operating results

Revenue: ¥482.8 billion (up 5.1% year-on-year)

Sales grew in the Japan segment owing to launches of Equa® and EquMet® and other factors. The North America segment, too, showed revenue growth as sales of LATUDA® and other products expanded. Likewise, the China segment and Other Regions segment registered increases in revenue.

Core operating profit: ¥72.0 billion (down 6.9% year-on-year)

Core operating profit decreased as a result of increases in selling, general and administrative expenses and research and development expenses incurred by Sumitovant and its subsidiaries, which were acquired through the Alliance despite an increase in gross profit on account of revenue growth.

Operating profit: ¥83.2 billion (up 43.8% year-on-year)

Operating profit showed a substantial increase because a cost reversal from change in the fair value of contingent consideration associated with company acquisitions surpassed the amount of impairment losses, though core operating profit decreased. The Group reported impairment losses on intangible assets, including in-process research and development and marketing rights, as part of a review of business plans in oncology and other areas. Meanwhile, the review of business plans led to a significant decline in the fair value of contingent consideration associated with acquisitions of Boston Biomedical, Tolero, and other companies, which resulted in the reversal of expenses.

Profit before taxes: ¥83.9 billion (up 29.1% year-on-year)

Profit before taxes showed higher growth than operating profit as finance income surpassed finance expenses.

Net profit: ¥35.9 billion (down 26.1% year-on-year)

The net profit took a downward turn as income tax expenses increased substantially though the profit before taxes increased. The increase of income tax expenses is attributed to the reversal of deferred tax assets recognized in the U.S. following the decision to discontinue the Phase 3 study of napabucasin in patients with pancreatic cancer, among other factors.

Net profit attributable to owners of the parent: ¥40.8 billion (down 16.2% year-on-year)

The net profit attributable to owners of the parent (less the

amount of losses attributable to non-controlling shareholders from net profit) increased greater than net profit because Sumitovant's subsidiaries with non-controlling interests registered loss.

The ratio of the net profit attributable to owners of the parent to revenue decreased by 2.2 points year-on-year to 8.4%.

Financial Condition

Summary of assets, liabilities, and equity

-Assets

Non-current assets increased by ¥427.3 billion from the previous fiscal year-end, as a result of in-process research and development and other intangible assets, as well as goodwill, with substantial increases from the purchase price allocation associated with acquiring Sumitovant and its subsidiaries, despite a decrease in deferred tax assets due to their reversal in the U.S. A significant increase in other financial assets under non-current assets as a result of acquiring a part of Roivant stocks was also responsible for the increase in non-current assets.

Current assets decreased by ¥9.2 billion from the previous fiscal year-end, as inventories and trade and other receivables increased, but other financial assets decreased due to declines in cash and cash equivalents and short-term loan receivables.

As a result, total assets increased by ¥418.2 billion from the previous fiscal year-end to ¥1,252.9 billion.

-Liabilities

Total liabilities increased by ¥284.2 billion from the previous fiscal year-end to ¥620.8 billion, as a result of a substantial increase in borrowings to finance payment of consideration for the Alliance and despite a decline in other financial liabilities due to the decrease in the fair value of contingent consideration.

-Equity

Total equity increased by ¥134.0 billion from the previous fiscal year-end to ¥632.1 billion. This is because equity attributable to owners of the parent increased to ¥529.5 billion, up by ¥31.3 billion from the previous fiscal year-end, as a result of an increase in retained earnings and ¥102.6 billion in equity attributable to non-controlling interests was recorded associated with acquiring Sumitovant.

The ratio of equity attributable to owners of the parent to total assets as of the end of the fiscal year under review was 42.3%.

Status of cash flows

-Net cash provided by operating activities

Cash flows provided by operating activities remained almost flat year-on-year at ¥46.1 billion, as profit before taxes

increased. However, factors that contributed to a decrease in cash, such as increases in inventories and trade and other receivables surpassed those contributing to an increase in cash, such as an increase in trade and other payables.

-Net cash used in investing activities

Cash flows used in investing activities increased by ¥277.6 billion year-on-year to ¥312.7 billion, primarily owing to the purchase of investments as a result of the acquisition of Roivant's shares as per the Alliance and to the payment for the acquisition of control of Sumitovant and its subsidiaries.

-Net cash provided by financing activities

Cash flows provided by financial activities increased by ¥259.7 billion year-on-year to ¥231.1 billion, primarily owing to a substantial increase in short-term borrowings payable as a result of financing to pay consideration for the Alliance.

-Cash and cash equivalents

As a result of the above, the balance of cash and cash equivalents as of March 31, 2020, was ¥101.7 billion, which represents a decrease of ¥35.6 billion from the previous fiscal year-end.

Allocation of the Company's profits

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

The Company's basic policy is to make 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 sustained business growth. In the MTBP, the Company aims for a 5-year average payout ratio of 20% or higher. Given the dividend policy and earnings results of the fiscal year under review, the Company paid a year-end dividend of 14 yen per share, resulting in annual dividend to 28 yen per share in fiscal 2019. Due to the upfront investments associated with the strategic alliance with Roivant, the Company anticipates that profit will decline during the period of the MTBP, and the payout ratio in the earnings forecasts for the fiscal year ending March 31, 2021 is expected to be at a high level in excess of 100%. The Company plans to review the business goals, including the payout ratio, during the fiscal year

Operating Results and Financial Condition, and Business Risks

ending March 31, 2021.

Forecasts for the year ending March 31, 2021 (July 2020 revision of initial forecasts)

	Billions of yen		
	FY 2019	FY2020 (Initial forecasts)	FY2020 Forecasts
Revenue	482.8	510.0	495.0
Core operating profit	72.0	33.0	33.0
Operating profit	83.2	24.0	24.0
Net profit	35.9	(14.0)	(12.0)
Net profit attributable to owners of the parent	40.8	7.0	9.0

The Company has included the impact of COVID-19 on earnings that can be estimated as of July 31, 2020 and revised the initial forecasts for the year ending March 31, 2021.

In Japan, despite the impacts of the National Health Insurance (NHI) drug price revisions and declines in sales of long-listed products, revenue is forecasted to increase due to sales expansion of Equa® and EquMet®, which were started sales in November 2019; to sales expansion of Trulicity® and LONASEN® tape; and to the launch of LATUDA®. On the other hand, revenue from products such as LATUDA® in North America and MEROPEN® in China is forecasted to decline due to the impact of COVID-19. Consolidated revenue is thus expected to increase by ¥12.2 billion year-on-year to ¥495.0 billion.

Core operating profit is forecasted to decrease by ¥39.0 billion year-on-year to ¥33.0 billion, as a result of a substantial increase in selling, general and administrative expenses, and research and development expenses as Sumitovant and its subsidiaries, which joined the Group in December 2019, will incur expenses on a full-year basis even though selling, general and administrative expenses will be lower than the initial forecast due to the impact of COVID-19.

Meanwhile, operating profit is forecasted to decrease by ¥59.2 billion year-on-year to ¥24.0 billion. This is because we expect to record expenses as the fair value of contingent consideration will increase in the year ending March 2021, whereas we recorded a reversal of expenses as the fair value of contingent consideration declined during the fiscal year under review.

Net profit is forecasted to decrease by ¥47.9 billion year-on-year to negative ¥12.0 billion due to a decline in income tax expenses. Net profit attributable to owners of the parent is forecasted to decrease by ¥31.8 billion year-on-year to ¥9.0 billion after deducting losses on non-controlling interests, which are expected to increase.

* Foreign currency exchange rates used for the forecasts are: 1 USD = 108.0 JPY (108.7 JPY in the fiscal year under review), 1 RMB = 15.5 JPY (15.6 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, cash flow and financial position (“operating results, etc.”) of Sumitomo Dainippon Pharma Group. The Group is aware that these risks could occur, works to prevent and minimize them and will take appropriate measures if they occur.

Forward-looking matters statements in this discussion reflect the judgement of the Group as of March 31, 2020. It is not an exhaustive discussion of all risks, and the Group could be impacted in the future by risks that are currently unpredictable or considered immaterial.

Risk relating to research and development of new products

(Note) See p.25 for more details on opportunities and risks for each research area.

The Group works to research and develop highly original and globally viable products. However, 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 also possible that some development projects, from the standpoint of efficacy, safety, etc., may be delayed or abandoned. Such cases involving research and development assets expected to become major products could have a significant and negative impact on the Group's operating results, etc.

While taking research and development risks into consideration, the Group concentrates research and development efforts on the three focus areas of Psychiatry & Neurology, Oncology, and Regenerative Medicine/Cell Therapy and is expanding its pipeline in those areas. Moreover, through the establishment of a system for the global management of development, the Group formulates strategic development plans and implements efficient clinical development. The Company reviews research and development policy appropriately through a committee system for confirming the advantages and disadvantages of plan revisions in time with transitional stages of development and other methods to manage its portfolio properly.

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®, which is a pillar of Group earnings, comprised 39% of Sumitomo Dainippon Pharma's consolidated revenue. If LATUDA® revenue falls due to the emergence of other strong competing products (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), or through other unexpected events such as impacts on the supply chain, including raw material procurement, it could have a significant and negative effect on the Group's operating results, etc.

Under the Mid-term Business Plan, the Group is working to establish growth engines. In addition to concentrating research and development efforts on the three focus areas of Psychiatry & Neurology, Oncology, and Regenerative Medicine/Cell Therapy, the Group aims to expand its pipeline, including the acquisition of late-stage development assets that can be expected to contribute early to revenue. The Group is also working to launch Frontier business aimed at the commercialization of healthcare solutions that provide new value to society with a focus on areas in which synergies with its pharmaceuticals business are expected. In its regional strategy, the Group is working to strengthen its business base with China as a third center in addition to the primary markets of Japan and North America.

Risk relating to intellectual property rights

The Group utilizes a wide range of intellectual property during the course of its R&D activities. However, if the Group is unable to acquire a sufficient scope of rights to its technology, a competitor evades the Group's intellectual property rights, or there is an external leak of trade secrets, including know-how that is strictly managed by the Company, due to unexpected circumstances, the Group could be unable to secure its competitive advantage. 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, the Group could be unable to adequately maintain its competitive advantage. If such risks manifested, it could have a significant and negative impact on the Group's operating results, etc. On the other hand, the Group understands there are rights to lawfully use intellectual property rights required for business activities. Nevertheless, there is the possibility that it could infringe the intellectual property rights of a third party unknown to the Group.

The Group is building a patent portfolio that not only includes the core substance patents, but also related patents, such as applications, manufacturing methods, and formulations, to comprehensively safeguard its products and development assets. Furthermore, in order to advance commercialization in the Regenerative Medicine/Cell Therapy field, the Group is studying the issues involved in acquiring rights to its technologies in this field and taking measures to acquire such rights.

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. Moreover, in the U.S., the world's largest market for ethical pharmaceuticals, pressure from federal and state governments and public opinion to reduce the price of branded drugs is mounting year after year, and there is the possibility that system reforms aimed at controlling drug prices will be decided and introduced. In China also, there is the possibility that healthcare system changes will be implemented with the aim of controlling pharmaceutical expenses, including an expansion in centralized drug purchasing by public institutions. The direction that these healthcare system reforms might take could have a significant and negative impact on the Group's operating results, etc. As a pharmaceutical company, the Group will observe the system in each country and respond appropriately in accordance with such systems.

Problems relating to adverse reactions

Pharmaceutical products are approved only after rigorous safety testing, at different stages of development, and rigorous reviews by the competent authorities in all the countries involved. These efforts notwithstanding, previously unreported adverse reactions are sometimes discovered only after a drug has already been marketed. The appearance of such unexpected adverse reactions once a product of the Group has been sold could have a significant and negative impact on the Group's operating results, etc. The Group uses a database to centrally manage and evaluate safety information collected in Japan and overseas and formulates the necessary measures to ensure pharmaceutical safety and appropriate use, leading to the timely implementation of safety measures. These initiatives are implemented as pharmacovigilance activities in compliance with Japan's Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices and Good Vigilance Practice (GVP).

Risks relating to quality

The Group manufactures products based on strict quality control. Nevertheless, if a serious quality issue occurs, it could have a significant and negative impact on the Group's operating results, etc. as a result of product recalls, administrative penalties, and the loss of social trust. The manufacture, shipment and global distribution of the Group's products are conducted in accordance with laws

Operating Results and Financial Condition, and Business Risks

and regulations related to pharmaceuticals and Good Manufacturing Practice (GMP), and undergo rigorous reviews and approval by the competent authorities including the Ministry of Health, Labour and Welfare in Japan, the Food and Drug Administration (FDA) in the U.S., and the European Medicines Agency (EMA) in Europe. Moreover, the Group has in place high levels of facility design and quality assurance systems that conform to strict global quality standards, including audits of overseas alliance partners and International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guidelines.

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, etc.

The Group has positioned promotion of compliance as the foundation for all business activities and strives to observe laws and regulations and corporate ethics. The Company has established Compliance Standards as a specific code of conduct for business activities. An Executive Officer in charge of Compliance has also been appointed to oversee compliance at the Company and at Group companies in Japan and overseas. The Executive Officer in charge of Compliance serves as chair of Compliance Committees at Group companies in Japan and Group companies overseas as well as the Compliance Committee of the Company and reports to the Board of

Directors on the activities of each committee.

Risk relating to litigation

There is always the possibility that a lawsuit may be brought in connection with the adverse effect of a pharmaceutical product, product liability, fair trade, etc., relating to the business activities of the Group. These 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, etc.

Closure 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, etc. The Group's plants have prepared emergency response procedure manuals based on the Business Continuity Plan (BCP) and act in accordance with the manuals.

Risk of impairment loss on non-financial assets

In order to achieve sustained growth, the Group engages in corporate acquisitions and in-licensing of development assets and records intangible assets, such as goodwill and in-process research and development, associated with these activities. In the event that the expected recoverable amount from acquisition or in-licensing is estimated to be lower than the book values of goodwill and intangible assets due to an expected decline in future profit, including suspension of development or failure to achieve the initial estimated profit, impairment loss will arise. Such cases could have a significant and negative impact on the Group's operating results, etc. The Group periodically assesses the values of such goodwill and intangible assets using impairment tests and applies the appropriate treatment.

Risk relating to financial assets

The Group owns financial assets including the shares of other companies. When the market value or fair value of owned financial assets is lower than the book value, impairment loss or loss on sale arises. Such losses could have a significant and negative impact on the Group's operating results, etc. The Company will not acquire any new holdings of shares in other companies, except for corporate alliances, building and maintaining business relationships with key business partners, and other cases when necessary for business purposes. The Company also periodically assesses changes in the valuation of such financial assets using impairment tests and applies the necessary treatment.

Impact of the financial market situation and foreign exchange fluctuations

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, etc. Furthermore, foreign exchange fluctuations may have a material impact on foreign currency-denominated assets and the conversion of operating results of consolidated subsidiaries into yen. The Group enters into exchange contracts to avoid foreign exchange risk.

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. 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, etc.

Important transactions that the Company conducts with its parent company are supervised appropriately through such means as obtaining the approval of a meeting of the Board of Directors attended by the independent directors in order to ensure fairness and rationality from the perspective of enhancing the Company's corporate value.

Risk relating to overseas operation, large-scale disasters and infectious disease, etc.

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, etc. In the event of facing a large-scale disaster or infectious disease pandemic, the Group may be unable to achieve business plans, and this could have a significant and negative impact on the Group's operating results, etc. To address risks that impact on business activities, the Company has formulated Risk Management Rule under which it is specified that the President oversees risk management as well as developing

risk management systems for each risk. In the event of a large-scale disaster or infectious disease pandemic, the Company immediately establishes a headquarters for countermeasures to build systems for a company-wide response and has established production and supply systems with a priority on the supply of products as the mission of a pharmaceutical company.

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, etc. resulting from compensation for damages, administrative sanctions, loss of social credibility, or the like. The Company has established in-house rules on the handling of records and information and IT security and continually provides education for employees in striving for the appropriate operation of these rules.

Risk relating to environmental protection

The Group uses a variety of chemical substances in research and development and in the manufacture of products. In the event of a serious environmental problem, it could have a significant and negative impact on the Group's operating results, etc. due to shutdown of operations, administrative penalties, and loss of social trust, etc. Moreover, in the event that expenses related to environmental protection increase due to future strengthening of environmental laws and regulations, measures to address risk related to climate change, and additional obligations to reduce environmental impact, it could have a significant and negative impact on the Group's operating results, etc. The Group complies with various environmental laws and regulations when engaging in business activities, and plants in Japan have obtained ISO 14001 certification, which is the international standard for environmental management systems. In addition, the Group engages in green product development and green facility design as well as operating green logistics guidelines to continue addressing environmental protection throughout the product lifecycle.

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, 2020 and 2019

		Millions of yen	
	Note	2019	2020
Revenue	4, 5	¥ 459,267	¥ 482,732
Cost of sales		113,553	129,673
Gross profit		345,714	353,059
Selling, general and administrative expenses	6	180,439	154,348
Research and development expenses		102,364	115,112
Other income	7	885	1,404
Other expenses	8	5,912	1,764
Operating profit		57,884	83,239
Finance income	9	7,369	3,568
Finance costs	9	207	2,860
Profit before taxes		65,046	83,947
Income tax expenses	10	16,419	48,029
Net profit		48,627	35,918
Net profit attributable to:			
Owners of the parent		48,627	40,753
Non-controlling interests		—	(4,835)
Net profit total		48,627	35,918
Earnings per share (yen)			
Basic earnings per share	11	122.39	102.58

Consolidated Statement of Comprehensive Income

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries
Years Ended March 31, 2020 and 2019

		Millions of yen	
	Note	2019	2020
Net profit		¥ 48,627	¥ 35,918
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	876	11,350
Remeasurements of defined benefit liability (asset)	12	(2,089)	46
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	12	8,766	(7,359)
Cash flow hedges	12	15	(23)
Total other comprehensive income		7,568	4,014
Total comprehensive income		56,195	39,932
Total comprehensive income attributable to:			
Owners of the parent		56,195	45,667
Non-controlling interests		—	(5,735)
Total comprehensive income		56,195	39,932

Consolidated Statement of Financial Position

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries
Years Ended March 31, 2020 and 2019

	Note	Millions of yen	
		2019	2020
Assets			
Non-current assets			
Property, plant and equipment	14, 17	¥ 59,485	¥ 65,748
Goodwill	15	99,348	169,046
Intangible assets	16	171,390	421,791
Other financial assets	18, 29	74,668	200,923
Income taxes receivables		2,562	—
Other non-current assets		3,277	4,173
Deferred tax assets	10	50,719	27,107
Total non-current assets		461,449	888,788
Current assets			
Inventories	19	66,889	79,368
Trade and other receivables	20, 29	118,760	134,491
Other financial assets	18, 29	43,750	28,717
Income taxes receivables		483	5,877
Other current assets		6,090	9,624
Cash and cash equivalents	21	137,296	101,708
Subtotal		373,268	359,785
Assets held for sale	13	—	4,305
Total current assets		373,268	364,090
Total assets		834,717	1,252,878
Liabilities and equity			
Liabilities			
Non-current liabilities			
Borrowings	22, 29	27,980	25,020
Other financial liabilities	17, 24, 29	80,387	41,306
Retirement benefit liabilities	26	23,613	23,870
Other non-current liabilities		6,425	7,212
Deferred tax liabilities	10	—	26,867
Total non-current liabilities		138,405	124,275
Current liabilities			
Borrowings	22, 29	2,960	272,960
Trade and other payables	23, 29	49,238	62,251
Other financial liabilities	17, 24, 29	8,673	13,906
Income taxes payable		15,723	22,637
Provisions	25	92,176	84,644
Other current liabilities		29,404	40,100
Total current liabilities		198,174	496,498
Total liabilities		336,579	620,773
Equity			
Share capital	28	22,400	22,400
Capital surplus	28	15,861	14,655
Treasury shares	28	(674)	(677)
Retained earnings	28	431,799	457,330
Other components of equity	28	28,752	35,777
Equity attributable to owners of the parent		498,138	529,485
Non-controlling interests		—	102,620
Total equity		498,138	632,105
Total liabilities and equity		¥ 834,717	¥ 1,252,878

Consolidated Statement of Changes in Equity

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries
Years Ended March 31, 2020 and 2019

	Note	Equity attributable to owners of the parent					Other components of equity	
		Share capital	Capital surplus	Treasury shares	Retained earnings	Net gain (loss) on revaluation of financial assets measured at fair value through other comprehensive income		
						Remeasurements of defined benefit liability (asset)		
Millions of yen								
Balance as of April 1, 2018		¥ 22,400	¥ 15,860	¥ (669)	¥ 396,037	¥ 31,735	¥ —	
Cumulative effects of changes in accounting policies		—	—	—	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	28	—	—	(6)	—	—	—	
Disposal of treasury shares	28	—	1	1	—	—	—	
Dividends	28	—	—	—	(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	—	
Net profit		—	—	—	40,753	—	—	
Other comprehensive income	12	—	—	—	—	11,350	46	
Total comprehensive income		—	—	—	40,753	11,350	46	
Purchase of treasury shares	28	—	—	(3)	—	—	—	
Dividends	28	—	—	—	(13,111)	—	—	
Acquisition of subsidiaries		—	—	—	—	—	—	
Transactions with non-controlling interests		—	(1,206)	—	—	—	—	
Reclassification from other components of equity to retained earnings		—	—	—	(2,111)	2,157	(46)	
Total transactions with owners		—	(1,206)	(3)	(15,222)	2,157	(46)	
Balance as of March 31, 2020		¥ 22,400	¥ 14,655	¥ (677)	¥ 457,330	¥ 46,118	¥ —	

	Note	Equity attributable to owners of the parent					Non-controlling interests	Total equity
		Other components of equity			Total	Total		
		Exchange differences on translation of foreign operations	Cash flow hedges	Total				
Millions of yen								
Balance as of April 1, 2018		¥ (12,619)	¥ (21)	¥ 19,095	¥ 452,723	¥ —	¥ 452,723	
Cumulative effects of changes in accounting policies		—	—	—	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	—	7,568	
Total comprehensive income		8,766	15	7,568	56,195	—	56,195	
Purchase of treasury shares	28	—	—	—	(6)	—	(6)	
Disposal of treasury shares	28	—	—	—	2	—	2	
Dividends	28	—	—	—	(11,124)	—	(11,124)	
Reclassification from other components of equity to retained earnings		—	—	2,089	—	—	—	
Total transactions with owners		—	—	2,089	(11,128)	—	(11,128)	
Balance as of March 31, 2019		(3,853)	(6)	28,752	498,138	—	498,138	
Net profit		—	—	—	40,753	(4,835)	35,918	
Other comprehensive income	12	(6,459)	(23)	4,914	4,914	(900)	4,014	
Total comprehensive income		(6,459)	(23)	4,914	45,667	(5,735)	39,932	
Purchase of treasury shares	28	—	—	—	(3)	—	(3)	
Dividends	28	—	—	—	(13,111)	—	(13,111)	
Acquisition of subsidiaries		—	—	—	—	107,783	107,783	
Transactions with non-controlling interests		—	—	—	(1,206)	572	(634)	
Reclassification from other components of equity to retained earnings		—	—	2,111	—	—	—	
Total transactions with owners		—	—	2,111	(14,320)	108,355	94,035	
Balance as of March 31, 2020		¥ (10,312)	¥ (29)	¥ 35,777	¥ 529,485	¥ 102,620	¥ 632,105	

Consolidated Statement of Cash Flows

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries
Years Ended March 31, 2020 and 2019

	Note	2019	2020
Millions of yen			
Cash flows from operating activities			
Net profit		¥ 48,627	¥ 35,918
Depreciation and amortization		13,976	17,365
Impairment losses		22,996	35,196
Changes in fair value of contingent consideration		(9,128)	(48,474)
Interest and dividend income		(3,702)	(3,564)
Interest expenses		178	699
Income tax expenses		16,419	48,029
(Increase) decrease in trade and other receivables		(3,630)	(16,374)
(Increase) decrease in inventories		(3,207)	(14,354)
Increase (decrease) in trade and other payables		(10,869)	15,241
Increase (decrease) in retirement benefits liabilities		(114)	338
Increase (decrease) in provisions		3,997	(5,703)
Others, net		(6,805)	5,436
Subtotal		68,738	69,753
Interest received		2,424	2,686
Dividends received		1,156	1,123
Interest paid		(144)	(1,526)
Income taxes paid		(23,463)	(25,908)
Net cash provided by operating activities		48,711	46,128
Cash flows from investing activities			
Purchase of property, plant and equipment		(9,265)	(7,722)
Proceeds from sales of property, plant and equipment		1,693	769
Purchase of intangible assets		(3,649)	(5,629)
Purchase of investments		(2,778)	(112,494)
Proceeds from sales and redemption of investments		—	1,623
Payments for acquisition of control of subsidiaries		—	(205,774)
Net decrease (increase) in short-term loan receivables		(21,050)	16,520
Others, net		—	23
Net cash used in investing activities		(35,049)	(312,684)
Cash flows from financing activities			
Net increase (decrease) in short-term borrowings	22	(3,500)	270,000
Repayments of long-term borrowings	22	(2,960)	(19,623)
Redemption of bonds	22	(10,000)	—
Repayments of lease liabilities	22	(1,059)	(4,837)
Dividends paid		(11,122)	(13,106)
Payments for acquisition of interest in a subsidiary from non-controlling interests		—	(1,350)
Others, net		(4)	(3)
Net cash provided by (used in) financing activities		(28,645)	231,081
Net increase (decrease) in cash and cash equivalents		(14,983)	(35,475)
Cash and cash equivalents at beginning of year	21	147,775	137,296
Effect of exchange rate changes on cash and cash equivalents		4,504	(113)
Cash and cash equivalents at end of year	21	¥ 137,296	¥ 101,708

Notes to Consolidated Financial Statements

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries
Years Ended March 31, 2020 and 2019

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, 2020. 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

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 23, 2020 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 15 and 16)
- Estimated useful lives of intangible assets (Note 3)
- Recoverability of deferred tax assets (Note 10)
- Measurement of defined benefit obligations (Note 26)
- Fair value of financial assets (Note 29)
- Accounting treatment and measurement of provisions (Note 25)
- Fair value of contingent consideration related to business combinations (Note 29)

(5) Changes in Significant Accounting Policies

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

Introduction or Revision of Standards and Interpretations		Overview of introduction or Revision
IFRS 16	Leases	Revised accounting standards for recognition of leases

Starting from the year ended March 31, 2020, the Group adopted IFRS 16 "Leases" (issued in January 2016, hereinafter "IFRS 16").

The Group adopted IFRS 16 by using the following transition method (modified retrospective approach) of IFRS 16.

- (i) To recognize the cumulative effect of adopting IFRS 16 at the date of initial application
- (ii) For leases previously classified as operating leases
 - (a) To measure the lease liability at the present value of the remaining lease payments, discounted using the lessee's incremental borrowing rate at the date of initial application.
 - (b) To measure and recognize the right-of-use asset by using either of the followings.
 - To recognize the carrying amount as if IFRS 16 had been applied since the commencement date, but discounted using the lessee's incremental borrowing rate at the date of initial application
 - To recognize the measurement amount of the lease liability, adjusted by the amount of any prepaid or accrued lease payments

In transitioning to IFRS 16, the Group chose the adoption of practical expedient which succeeded the previous judgement related to whether an arrangement is a lease.

As a result, the impact on the financial position at the date of initial application of the Group is that Total assets and Total liabilities in the Consolidated Statement of Financial Position increased by ¥14,626 million and ¥14,626 million, respectively. However, such impact on the performance is immaterial.

The weighted average incremental borrowing rate applied to lease liabilities at the date of initial application is 1.5%.

The following is a difference between the total future minimum lease payments of non-cancellable operating lease at the end of the annual reporting period immediately preceding the date of initial application and lease liabilities recognized in the Consolidated Statement of Financial Position at the date of initial application.

	Millions of yen
Total future minimum lease payments of non-cancellable operating lease as of March 31, 2019	¥ 9,543
Discounted using the incremental borrowing rate as of April 1, 2019	8,790
Finance lease obligations recognized as of March 31, 2019	2,043
Additional recognition of lease liabilities by revising the lease term	6,525
Lease liabilities as of April 1, 2019	¥ 17,358

(6) New Standards and Interpretations Issued but Not Yet Applied

There are no new standards and interpretations that have been issued or amended but not yet applied by the Group, which may have a material impact on the consolidated financial statements of the Group.

(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, 2020 and 2019

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.

A Change in ownership interest of a subsidiary, without losing control, is accounted for as an equity transaction. Differences between adjustment amount of non-controlling interests and fair value of the consideration are recognized directly as equity attributed to owner of the parent. In the event of losing control, any gain or loss arising from losing control is recognized in profit or loss.

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.

Notes to Consolidated Financial Statements

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries
Years Ended March 31, 2020 and 2019

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.

(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. When there are dilutive potential shares that have an antidilutive effect, such potential shares are not included in the calculation of diluted earnings per share.

(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
- Right-of-use assets The shorter of the estimated useful lives or lease terms

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 assesses whether the contract is, or contains, a lease based on whether the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

If it is determined that a contract is, or contains, a lease, the Group recognizes right-of-use assets and lease liabilities at the commencement date of the lease.

(1) Right-of-use asset

The right-of-use asset is measured at cost. The cost of the right-of-use asset is measured at the amount of the initial measurement of the lease liability at the commencement date of the lease adjusted for the initial direct costs, etc.

The Group applies a cost model for subsequent measurement of right-of-use asset. After initial recognition, the right-of-use asset is depreciated using the straight-line method over the shorter of lease term of underlying asset or its estimated useful life.

The right-of-use asset is stated at cost less accumulated depreciation and accumulated impairment losses and included in property, plant and equipment in the Consolidated Statement of Financial Position.

(2) Lease liability

The lease liability is initially recognized at the present value of the lease payments that are not paid at the commencement date. The Group normally uses the incremental borrowing rate as a discount rate. After the initial recognition, the lease liability is measured by increasing and reducing the carrying amount to reflect interest on the lease liability and the lease payments made by using the effective interest method. The lease liability is included in other financial liabilities in the Consolidated Statement of Financial Position.

Lease payments are allocated between finance costs which are the amount that produces a constant periodic rate of interest on the remaining balance of the lease liability, and the payment portion of lease liabilities. Finance costs are separated from depreciation expenses of the right-of-use asset in the Consolidated Statement of Profit or Loss.

As for short-term leases and leases of low-value assets, the Group basically does not recognize right-of-use assets and lease liabilities but charges the lease payments associated with short-term leases and leases of low-value assets to the net profit or loss on a straight-line basis over the lease term.

For the year ended March 31, 2019, lease transactions were accounted for based on the accounting policies set out as below.

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

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

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

(8) Goodwill

Initial measurement of goodwill is stated in (1) Basis of consolidation 3. Business Combinations.

Goodwill is carried at cost less any accumulated impairment losses.

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

(9) Intangible assets

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

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

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

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

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

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

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

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

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

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

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

(10) Impairment of non-financial assets

The Group assesses whether there is any indication that non-financial assets other than inventories,

retirement benefit assets and deferred tax assets may be impaired.

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

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

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

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

Impairment losses on goodwill are not reversed.

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

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

(11) Financial instruments

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

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

(iii) Derecognition

A financial asset is derecognized when it meets one of the following conditions:

- the contractual rights to the cash flows from the financial assets expire; or
- the Group transfers the financial assets and substantially all the risks and rewards related to the ownership of the financial assets.

(iv) Impairment

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

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

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

2. Financial liabilities

(i) Initial recognition and measurement

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

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

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

(b) Financial liabilities measured at amortized cost

Financial liabilities other than financial liabilities measured at fair value through profit or loss.

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

(ii) Subsequent measurement

After the initial recognition, financial liabilities are measured as follows:

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

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

(b) Financial liabilities measured at amortized cost

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

(iii) Derecognition

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

3. Derivatives

The Group uses derivatives to hedge foreign currency risk exposures. Such derivatives used by the Group are foreign currency forward contracts. However, the Group does not use derivatives for speculative purpose. Derivatives are initially recognized at fair value and the related transaction costs

are recognized as expenses when incurred. Derivatives not qualified for hedge accounting are measured at fair value after initial recognition and the change in fair value is recognized in profit or loss.

4. Hedge accounting

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

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

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

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

(12) Inventories

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

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

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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) Share-based payments

Certain consolidated subsidiaries in the Group introduce the equity-settled share-based payment plans.

In the equity-settled share-based payments, the service received are measured at the fair value of the equity instruments at the date of grant. The fair value of the equity instruments is recognized as an expense from the date of grant over the vesting period while the same amount is recognized as an increase in equity.

(16) 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.

(17) 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.

(18) Capital

1. Ordinary share

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

2. Treasury share

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

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

4. Operating Segments

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

Core operating profit is operating profit after deducting gains and losses arising from extraordinary items prescribed by the Group. The amount deducted as extraordinary items mainly represents impairment losses, business structure improvement expenses, 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 Note3 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, 2019

	Millions of yen						
	2019						
	Reportable segments					Other business (Note)	Total
	Pharmaceutical business				Subtotal		
	Japan	North America	China	Other Regions			
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.

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2. Year ended March 31, 2020

	Millions of yen						
	2020						
	Reportable segments					Other business (Note)	Total
	Pharmaceutical business						
Japan	North America	China	Other Regions	Subtotal			
Revenues from external customers	¥ 139,675	¥ 262,295	¥ 28,607	¥ 14,786	¥ 445,363	¥ 37,369	¥ 482,732
Inter-segment revenues	76	—	—	—	76	53	129
Total	139,751	262,295	28,607	14,786	445,439	37,422	482,861
Segment profit (Core segment profit)	22,898	117,514	14,408	6,396	161,216	3,202	164,418
Other items							
Depreciation and amortization	5,329	6,830	723	721	13,603	290	13,893
Impairment losses	—	35,196	—	—	35,196	—	35,196

(Note) The "Other business" category incorporates operations not included in reportable segments, including food ingredients, food additives, chemical product materials, veterinary drugs 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, 2019	Year ended March 31, 2020
Total of reportable segments	¥ 420,936	¥ 445,439
Revenue of Other Business	38,437	37,422
Elimination of inter-segment revenue	(106)	(129)
Revenue on the consolidated financial statements	¥ 459,267	¥ 482,732

Profit	Millions of yen	
	Year ended March 31, 2019	Year ended March 31, 2020
Total of reportable segments	¥ 156,959	¥ 161,216
Segment profit of Other Business	3,014	3,202
Elimination of inter-segment profit	42	19
Research and development expenses (Note)	(82,891)	(92,607)
Gains on business transfers	148	157
Others	27	(5)
Core operating profit	77,299	71,982
Change in fair value of contingent consideration	9,128	48,474
Impairment losses	(22,996)	(35,196)
Other income	710	1,252
Other expenses	(5,912)	(1,764)
Others	(345)	(1,509)
Operating profit in the consolidated financial statements	¥ 57,884	¥ 83,239

(Note) The Group does not allocate Research and development expenses to the operating segments because such expenses are managed on a global basis. Differences from Research and development expenses on Consolidated Statement of Profit or Loss consist of impairment losses and expenses related to research and development excluded from calculation of core operating profit.

Millions of yen

Other items	Total of reportable segments		Other business		Adjustments		Amount in the consolidated financial statements	
	Year ended March 31, 2019	Year ended March 31, 2020	Year ended March 31, 2019	Year ended March 31, 2020	Year ended March 31, 2019	Year ended March 31, 2020	Year ended March 31, 2019	Year ended March 31, 2020
Depreciation and amortization	¥ 10,807	¥ 13,603	¥ 88	¥ 290	¥ 3,081	¥ 3,472	¥ 13,976	¥ 17,365

(4) Revenues

The details of revenues from external customers are as follows:

Millions of yen

	Year ended March 31, 2019	Year ended March 31, 2020
Sale of goods	¥ 454,088	¥ 474,543
Revenue arising from intellectual property rights	3,290	3,665
Other	1,889	4,524
Total	¥ 459,267	¥ 482,732

(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, 2019	Year ended March 31, 2020
Pharmaceuticals	¥ 420,865	¥ 445,363
Others	38,402	37,369
Total	¥ 459,267	¥ 482,732

(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, 2019	Year ended March 31, 2020
Japan	¥ 170,916	¥ 180,678
North America	252,066	261,630
U.S.A. in North America	247,191	256,427
Others	36,285	40,424
Total	¥ 459,267	¥ 482,732

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, 2019	As of March 31, 2020
Japan	¥ 75,973	¥ 67,263
North America	258,662	590,973
U.S.A. in North America	257,120	589,409
Others	1,427	2,522
Total	¥ 336,062	¥ 660,758

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(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:

	Reportable segment	Millions of yen	
		Year ended March 31, 2019	Year ended March 31, 2020
McKesson Corporation	North America	¥ 84,453	¥ 87,812
Cardinal Health Inc.	North America	69,025	75,502
AmerisourceBergen Corporation	North America	66,692	65,110

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						
	Japan	North America	China	Other Regions	Subtotal		
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.

Year ended March 31, 2020

	Millions of yen						
	Reportable segments					Other business (Note)	Total
	Pharmaceutical business						
	Japan	North America	China	Other Regions	Subtotal		
Sales of goods	¥ 135,215	¥ 261,080	¥ 28,389	¥ 12,490	¥ 437,174	¥ 37,369	¥ 474,543
Revenue arising from intellectual property rights	154	1,215	—	2,296	3,665	—	3,665
Other	4,306	—	218	—	4,524	—	4,524
Total	¥ 139,675	¥ 262,295	¥ 28,607	¥ 14,786	¥ 445,363	¥ 37,369	¥ 482,732

(Note) The "Other business" category incorporates operations not included in reportable segments, including food ingredients, food additives, chemical product materials, veterinary drugs, and other products.

(2) Contract Balances

Contract balances arising from contracts with customers are as follows:

	Millions of yen	
	As of March 31, 2019	As of March 31, 2020
Receivables from contracts with customers		
Accounts receivable and notes receivable	¥ 115,250	¥ 128,478
Contract assets	810	970
Contract liabilities	—	4,352

Receivables from contracts with customers and contract assets were included in "Trade and other receivable" and contract liabilities were included in "Other liabilities".

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.

Contract liabilities are the consideration of lump sum payments received arising from agreements related to some technology licensing-out agreements for which the performance obligation has not yet satisfied. Such consideration is recognized as revenue at the point of time when the performance obligations are satisfied, such as delivery the result of clinical trial related to these technology licensing-out agreements.

There was no revenue recognized during the year ended March 31, 2019 and 2020 that was included in contract liability balance at the beginning of the fiscal years ended March 31, 2019 and 2020. Also, there are no significant amounts of revenue recognized during the year ended March 31, 2019 and 2020 from performance obligations satisfied (or partially satisfied) in the prior fiscal years.

(3) Transaction price allocated to the remaining performance obligations

As there are no transactions with expected revenue recognition period over one year, information related to remaining performance obligations are not disclosed. Also, there are no significant amounts in consideration from contracts with customers that are not included in transaction prices.

(4) 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, 2019	Year ended March 31, 2020
Salaries and bonuses	¥ 61,439	¥ 65,763
Retirement benefit expenses	5,107	5,160
Advertising and promotion expenses	37,975	37,745
Depreciation and amortization	7,858	11,272
Impairment losses	3,424	12,102
Change in fair value of contingent consideration (Note)	(9,128)	(48,474)
Others	73,764	70,790
Total	¥ 180,439	¥ 154,348

(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 29 Financial Instruments.

7. Other Income

The details of other operating income are as follows:

	Millions of yen	
	Year ended March 31, 2019	Year ended March 31, 2020
Gain on sale of property, plant and equipment	¥ 418	¥ 317
Others	467	1,087
Total	¥ 885	¥ 1,404

8. Other Expenses

The details of other operating expenses are as follows:

	Millions of yen	
	Year ended March 31, 2019	Year ended March 31, 2020
Donation	¥ 657	¥ 772
Business structure improvement expenses (Note)	3,806	—
Others	1,449	992
Total	¥ 5,912	¥ 1,764

(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 year ended March 31, 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, 2019	Year ended March 31, 2020
Interest income		
Financial assets at amortized cost	¥ 2,546	¥ 2,441
Dividend income		
Financial asset at fair value through other comprehensive income	1,156	1,123
Exchange gain (net)	3,667	—
Others	—	4
Total	¥ 7,369	¥ 3,568

(2) Finance costs

The details of finance costs are as follows:

	Millions of yen	
	Year ended March 31, 2019	Year ended March 31, 2020
Interest expenses		
Financial liabilities at amortized cost	¥ 178	¥ 699
Exchange loss (net)	—	1,134
Other	29	1,027
Total	¥ 207	¥ 2,860

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, 2019	As of March 31, 2020
Deferred tax assets	¥ 50,719	¥ 27,107
Deferred tax liabilities	—	26,867
Net deferred tax assets	¥ 50,719	¥ 240

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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, 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 profits 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.

Years ended March 31, 2020

	Millions of yen				
	As of April 1, 2019	Recognized in profit or loss	Recognized in other comprehensive income	Others (Note)	As of March 31, 2020
Outsourced research expenses	¥ 12,206	¥ (2,860)	¥ —	¥ —	¥ 9,346
Inventories	17,099	5,574	—	(17)	22,656
Property, plant and equipment	1,931	(74)	—	(25)	1,832
Intangible assets	(16,863)	5,014	—	(26,493)	(38,342)
Other financial assets	(13,059)	(33)	(4,974)	283	(17,783)
Accrued expenses and provisions	12,760	(6,503)	—	(195)	6,062
Retirement benefits	8,079	220	(22)	(3)	8,274
Tax loss carryforwards	18,598	(12,271)	—	(376)	5,951
Tax credits	7,022	(6,673)	—	(145)	204
Undistributed earnings of foreign subsidiaries	(624)	(286)	—	—	(910)
Others	3,570	(470)	—	(150)	2,950
Total	¥ 50,719	¥ (18,362)	¥ (4,996)	¥ (27,121)	¥ 240

(Note) Others include exchange differences on translation of foreign operations. "Others" in intangible assets include deferred tax liabilities increased by business combinations of (¥27,055 million).

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, 2019	As of March 31, 2020
Tax loss carryforwards	¥ —	¥ 31,389
Tax credit carryforwards	5,389	11,968
Deductible temporary differences	11	17,457

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, 2019	As of March 31, 2020
Not later than 1 year	¥ —	¥ 2
Later than 1 year and not later than 2 years	—	21
Later than 2 years and not later than 3 years	—	42
Later than 3 years and not later than 4 years	—	—
Later than 4 years	—	31,324
Total	¥ —	¥ 31,389

(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, 2019	As of March 31, 2020
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	5,389	11,968
Total	¥ 5,389	¥ 11,968

5. Recoverability of deferred tax assets

Deferred tax assets as of March 31, 2020 was ¥70,015 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, 2019 and 2020.

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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, 2019	Year ended March 31, 2020
Current tax expenses (Note 1)	¥ 24,699	¥ 29,667
Deferred tax expense		
Origination and reversal of temporary Differences	(8,280)	(4,978)
Assessment of the recoverability of deferred tax assets (Note 2)	—	23,340
Subtotal	(8,280)	18,362
Total	¥ 16,419	¥ 48,029

(Note) 1. On March 27, 2020, "The Coronavirus Aid, Relief, and Economic Security (CARES) Act" (the "Act") was enacted in the United States of America. The main provisions of the Act that impact on the year ended March 31, 2020 are as follows:
(Carryback of net operating tax losses)

The Act allows a five-year carryback of net operating tax losses arising in tax years beginning after January 1, 2018 and before December 31, 2020.

As a result, the effect on carryback of net operating tax losses of (¥4,040 million) (profit) was included in the current tax expenses for the year ended March 31, 2020.

2. This is due to review of the recoverability of deferred tax assets in a certain subsidiary of the Company.

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, 2019 and 2020. The normal statutory tax rate based on these taxes is 30.6% for the years ended March 31, 2019 and March 31, 2020. However, overseas subsidiaries are subject to income taxes in their respective countries of domicile.

	Year ended March 31, 2019	Year ended March 31, 2020
Normal statutory tax rate	30.6%	30.6%
Permanent non-deductible expenses such as entertainment expenses	1.8%	1.6%
Permanent non-taxable income such as dividend received	(0.3%)	(0.1%)
Tax credit for research and development expenses	(6.5%)	(10.2%)
Changes in unrecognized deferred tax assets	(4.9%)	41.9%
Difference of subsidiaries' applicable income tax rates	7.5%	14.1%
Changes in tax effect of undistributed earnings of subsidiaries	—%	0.3%
Effect of change in fair value of contingent consideration	(3.6%)	(15.5%)
Effect of the CARES Act	—%	(4.8%)
Others	0.6%	(0.7%)
Effective tax rate	25.2%	57.2%

11. Earnings per Share

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

	Year ended March 31, 2019	Year ended March 31, 2020
The basis for calculation of basic earnings per share		
Net profit attributable to owners of the parent (Millions of yen)	¥ 48,627	¥ 40,753
Amounts not attributable to ordinary shareholders of the parent (Millions of yen)	—	—
Net profit used to calculate basic earnings per share (Millions of yen)	48,627	40,753
Weighted average number of ordinary shares (Thousands of shares)	397,297	397,295
Earnings per share		
Basic earnings per share (Yen)	122.39	102.58

(Note) Dilutive earnings per share is not disclosed as there are no shares with dilutive effect. As there are potential shares that have an antidilutive effect for the year ended March 31, 2020, they are not included in calculation of dilutive earnings per share. These potential shares are stock options issued by certain subsidiaries. The details are presented in Note 27, Share-based payments.

12. Other Comprehensive Income

The movement of other comprehensive income is as follows:

	Millions of yen	
	Year ended March 31, 2019	Year ended March 31, 2020
Net gain (loss) on revaluation of financial assets measured at fair value through other comprehensive income		
Amounts arising during the year	¥ 1,217	¥ 16,336
Tax effect	(341)	(4,986)
Net gain (loss) on revaluation of financial assets measured at fair value through other comprehensive income	876	11,350
Remeasurements of defined benefit liability (asset)		
Amounts arising during the year	(3,007)	68
Tax effect	918	(22)
Remeasurements of defined benefit liability (asset)	(2,089)	46
Exchange differences on translation of foreign operations		
Amounts arising during the year	8,766	(7,359)
Exchange differences on translation of foreign operations	8,766	(7,359)
Cash flow hedges		
Amounts arising during the year	24	(35)
Tax effect	(9)	12
Cash flow hedges	15	(23)
Total	¥ 7,568	¥ 4,014

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13. Assets held for sale

The Group classifies a non-current asset or disposal group that will be recovered principally through a sales transaction rather than through continuously being used as assets held for sale only when it is available for immediate sale in its current condition and it is highly probable that the sale will occur. Non-current assets or disposal groups classified as held for sale are measured at the lower of the carrying amount and the fair value less costs to sell.

Property, plant and equipments and intangible assets classified as assets or disposal groups held for sale are not depreciated or amortized. Assets held for sale and its liabilities are separately presented from other assets and other liabilities, as current items in the Consolidated Statement of Financial Position.

The details of assets held for sale are as follows:

	Millions of yen	
	As of March 31, 2019	As of March 31, 2020
Assets held for sale		
Property, plant and equipment	—	¥ 4,305
Total	—	¥ 4,305

Property, plant and equipment related to the Ibaraki Plant held by the Company are classified as non-current assets held for sale as of March 31, 2020.

14. 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	Right- of-use assets	Total
Balance as of April 1, 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
Others	(15)	60	(120)	—	—	—	(75)
Balance as of March 31, 2019	95,984	83,575	30,387	5,089	1,992	—	217,027
Changes in accounting policies	—	(2,820)	—	—	—	14,775	11,955
Balance as of April 1, 2019	95,984	80,755	30,387	5,089	1,992	14,775	228,982
Additions	224	142	290	—	5,251	2,414	8,321
Acquisition through business combinations	198	166	428	—	—	2,505	3,297
Transfer from construction in progress	1,486	2,358	1,488	—	(5,332)	—	—
Sales and disposals	(275)	(5,215)	(1,830)	—	—	(1,226)	(8,546)
Transfer to assets held for sale	(16,932)	(17,291)	(1,835)	(250)	—	—	(36,308)
Foreign currency translation differences	(284)	(140)	(147)	(8)	(11)	(227)	(817)
Others	7	3	2	—	21	—	33
Balance as of March 31, 2020	¥ 80,408	¥ 60,778	¥ 28,783	¥ 4,831	¥ 1,921	¥ 18,241	¥ 194,962

2. Accumulated depreciation and accumulated impairment losses

Millions of yen

	Buildings and structures	Machinery and vehicles	Tools, furniture and fixtures	Land	Construction in progress	Right-of-use assets	Total
Balance as of April 1, 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)
Others	13	(56)	115	—	—	—	72
Balance as of March 31, 2019	(59,111)	(72,889)	(25,451)	(64)	(27)	—	(157,542)
Depreciation	(2,764)	(1,791)	(1,956)	—	—	(3,989)	(10,500)
Impairment losses	—	(597)	(31)	—	—	—	(628)
Sales and disposals	243	4,751	1,755	—	—	543	7,292
Transfer to assets held for sale	12,877	17,291	1,835	—	—	—	32,003
Foreign currency translation differences	124	101	107	—	—	17	349
Others	(19)	565	(73)	—	—	(661)	(188)
Balance as of March 31, 2020	¥ (48,650)	¥ (52,569)	¥ (23,814)	¥ (64)	¥ (27)	¥ (4,090)	¥ (129,214)

3. Carrying amount

Millions of yen

	Buildings and structures	Machinery and vehicles	Tools, furniture and fixtures	Land	Construction in progress	Right-of-use assets	Total
Balance as of April 1, 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
Balance as of March 31, 2020	¥ 31,758	¥ 8,209	¥ 4,969	¥ 4,767	¥ 1,894	¥ 14,151	¥ 65,748

(Note) 1. There is no capitalized borrowing cost for property, plant and equipment for the years ended March 31, 2019 and 2020.

2. Details of commitment in respect of acquisitions of property, plant and equipment are presented in Note 30. Commitment.

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

(2) Impairment losses

Impairment losses recognized for the year ended March 31, 2019 and 2020 were ¥492 million and ¥628 million, respectively. Impairment loss was recorded in Cost of sales, and Research and development expenses in the Consolidated Statement of Profit or Loss.

Impairment losses recognized for the year ended March 31, 2019 amounting to ¥492 million 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.

Impairment losses recognized for the year ended March 31, 2020 amounting to ¥628 million were recorded in Cost of sales in the Consolidated Statement of Profit or Loss. Impairment losses represented a reduction of carrying amount of 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 North America segment of pharmaceutical business.

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15. 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, 2019	Year ended March 31, 2020
Beginning balance	¥ 95,097	¥ 99,348
Acquisition through business combinations	—	72,228
Foreign currency translation differences	4,251	(2,530)
Ending balance	¥ 99,348	¥ 169,046

2. Accumulated impairment losses

	Millions of yen	
	Year ended March 31, 2019	Year ended March 31, 2020
Beginning balance	¥ —	¥ —
Impairment losses	—	—
Foreign currency translation differences	—	—
Ending balance	¥ —	¥ —

3. Carrying amount

	Millions of yen
Balance as of April 1, 2018	¥ 95,097
Balance as of March 31, 2019	99,348
Balance as of March 31, 2020	¥ 169,046

(2) Significant goodwill

Significant goodwill recognized in the Consolidated Statement of Financial Position arose from the acquisition of Sumitovant Biopharma Ltd., 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, 2019	As of March 31, 2020
Sumitovant Biopharma Ltd.	¥ —	¥ 71,657
Sepracor Inc.	69,891	68,512
Tolero Pharmaceuticals, Inc.	¥ 21,949	¥ 21,516

(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, 2019 and 2020 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, 2019	As of March 31, 2020
North America (excluding oncology area)	¥ 75,048	¥ 145,225
North America (oncology area)	24,300	23,821
Total	¥ 99,348	¥ 169,046

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, 2019 and 2020, 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 9.5% - 17.0% and 13.8% -20.0% as of March 31, 2019 and 2020, 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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16. 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, 2018	¥ 207,910	¥ 13,050	¥ 238	¥ 221,198
Individual acquisitions	334	2,905	10	3,249
Sales and disposals	(1)	(256)	—	(257)
Foreign currency translation differences	8,293	251	—	8,544
Others	566	4	—	570
Balance as of March 31, 2019	217,102	15,954	248	233,304
Individual acquisition	3,043	2,661	—	5,704
Acquisitions through business combinations	290,646	997	—	291,643
Sales and disposals	(3,856)	(2,242)	—	(6,098)
Foreign currency translation differences	(6,339)	(185)	(2)	(6,526)
Balance as of March 31, 2020	¥ 500,596	¥ 17,185	¥ 246	¥ 518,027

2. Accumulated amortization and accumulated impairment losses

	Millions of yen			
	Intangible assets related to products	Software	Other	Total
Balance as of April 1, 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)
Others	(570)	(4)	—	(574)
Balance as of March 31, 2019	(51,655)	(10,085)	(174)	(61,914)
Amortization	(4,438)	(2,417)	(10)	(6,865)
Impairment losses	(34,568)	—	—	(34,568)
Sales and disposals	3,848	2,134	—	5,982
Foreign currency translation differences	1,010	124	1	1,135
Others	—	(6)	—	(6)
Balance as of March 31, 2020	¥ (85,803)	¥ (10,250)	¥ (183)	¥ (96,236)

3. Carrying amount

Millions of yen				
	Intangible assets related to			
	products	Software	Other	Total
Balance as of April 1, 2018	¥ 184,750	¥ 4,856	¥ 75	¥ 189,681
Balance as of March 31, 2019	165,447	5,869	74	171,390
Balance as of March 31, 2020	¥ 414,793	¥ 6,935	¥ 63	¥ 421,791

(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, 2019 and 2020 were ¥141,419 million, and ¥406,254 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, 2019	As of March 31, 2020
Myovant Sciences Ltd.		
relugolix	¥ —	¥ 175,075
Urovant Sciences Ltd.		
vibegron	—	109,028
Cynapsus Therapeutics Inc.		
APL-130277 (apomorphine hydrochloride)	55,156	54,068
Tolero Pharmaceuticals, Inc.		
DSP-2033 (alvocidib)	26,640	8,705
TP-0903	16,872	16,539
Boston Biomedical, Inc.		
BBI608 (napabucasin)	¥ 28,194	¥ 27,638

The above table mainly represent the intangible assets related to products that are not yet available for use arising from the acquisition of Myovant Sciences Ltd., Urovant Sciences Ltd., 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 43.

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 6.3% - 17.0% and 6.0%-19.0% as of March 31, 2019 and 2020, 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.

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-process research and development of sublingual film formulation of apomorphine hydrochloride (Product code: APL-130277), which is aiming for a New Drug Application (NDA) for the purpose of converting 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-process research and development of apomorphine hydrochloride, 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%.

Impairment losses for the year ended March 31, 2020 amounting to ¥34,568 million were recorded as Selling, general and administrative expenses and research and development expenses in the Consolidated Statement of Profit or Loss, and were ¥12,102 million and ¥22,466 million, respectively. The impairment losses were on patent rights of products regarding North America segment of pharmaceutical business amounting to ¥12,102 million and impairment loss on in-process research and development of alvocidib (product code: DSP-2033) amounting to ¥17,394 million, which is being developed as a small molecule inhibitor of cyclin-dependent kinase 9 (CDK9), anti-cancer drug amcasertib (product code: BBI503) amounting to ¥1,739 million and regenerative cell medicine SB623 for chronic stroke in North America (the United States and Canada) amounting to ¥3,333 million in North America segment of pharmaceutical business.

As for patent rights of products and in-process research and development of alvocidib, the carrying amount were reduced to the extent of the recoverable amount of ¥4,270 million and ¥8,705 million, respectively as the expected profitability would not be achieved. As for amcasertib, the total carrying amount is reduced due to the discontinuation of its clinical development. As for SB623, the total carrying amount is reduced due to the terminate the joint development and license agreement and return the rights in North America. The recoverable amount is measured based on value in use, using the pre-tax discount rate of 11.0% to 19.0%.

As for in-process research and development excluding the above, 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.

17. Leases

The Group mainly uses offices and warehouses under lease contracts. Certain lease contracts contain renewal options after termination of lease terms. There are no escalation clauses and any significant restrictions provided in the lease contracts.

Leases as a lessee

(1) Amounts recognized in profit or loss

	Millions of yen
	Year ended March 31, 2020
Depreciation	¥ 3,989
Interest expenses on lease liabilities	261
Expenses related to short-term leases	232
Expenses related to leases of low-value assets	716
Variable lease payments not included in the measurement of lease liabilities	74
Income from sublease of right-of-use assets	646

(2) Right-of-use assets

The movements in acquisition cost, accumulated depreciation, accumulated impairment losses and carrying amounts of right-of-use assets included in property, plant and equipment are as follows:

1. Acquisition cost

	Millions of yen			
	Buildings and structures	Machinery and vehicles	Tools, furniture and fixtures	Total
Balance as of April 1, 2019	¥ 10,862	¥ 3,913	—	¥ 14,775
Additions	567	1,847	—	2,414
Acquisitions through business combinations	2,505	—	—	2,505
Sales and disposals	(72)	(1,154)	—	(1,226)
Foreign currency translation differences	(181)	(46)	—	(227)
Balance as of March 31, 2020	¥ 13,681	¥ 4,560	—	¥ 18,241

(Note) Balance as of April 1, 2019 includes buildings and structures amounting to ¥10,862 million and machinery and vehicles amounting to ¥1,093 million, which are amounts related to right-of-use assets that had been recorded in acquisition cost of property, plant and equipments until March 31, 2019 and the effect on the adoption of IFRS16 from April 1, 2019.

2. Accumulated depreciation and accumulated impairment losses

	Millions of yen			
	Buildings and structures	Machinery and vehicles	Tools, furniture and fixtures	Total
Balance as of April 1, 2019	¥ —	¥ (661)	—	¥ (661)
Depreciation	(2,888)	(1,101)	—	(3,989)
Sales and disposals	—	543	—	543
Foreign currency translation differences	4	13	—	17
Balance as of March 31, 2020	¥ (2,884)	¥ (1,206)	—	¥ (4,090)

(Note) Balance as of April 1, 2019 includes amounts related to right-of-use assets that had been recorded in accumulated depreciation and accumulated impairment losses of property, plant and equipments until March 31, 2019.

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3. Carrying amount

	Millions of yen			Total
	Buildings and structures	Machinery and vehicles	Tools, furniture and fixtures	
Balance as of April 1, 2019	¥ 10,862	¥ 3,252	—	¥ 14,114
Balance as of March 31, 2020	¥ 10,797	¥ 3,354	—	¥ 14,151

(3) Lease liabilities

The contractual maturities of lease liabilities are as follows:

	Millions of yen
	As of March 31, 2020
Contractual undiscounted cash flows	
Within 1 year	¥ 6,137
Over 1 year, within 5 years	9,021
Over 5 years	3,704
Balance of undiscounted lease liabilities	18,862
Balance of lease liabilities	17,279
Lease liabilities (non-current)	11,493
Lease liabilities (current)	5,786

(4) Amounts recognized in the Consolidated Statement of Cash Flows

The total cash outflows for leases are as follows:

	Millions of yen
	Year ended March 31, 2020
Repayments of lease liabilities	¥ 4,837
Interest expenses on lease liabilities paid	245
Others	1,022
Total	¥ 6,104

Information related to leases for the year ended March 31, 2019 is as follows:

(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, 2019	As of March 31, 2019
Within 1 year	¥ 765	¥ 737
Over 1 year, Within 5 years	1,330	1,306
Over 5 years	—	—
Total	¥ 2,095	¥ 2,043
Less: finance expenses	52	
Present value of total minimum lease payments	2,043	
Finance lease obligations (non-current)	1,306	
Finance lease obligations (current)	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, 2019
Within 1 year	¥ 1,293
Over 1 year, Within 5 years	4,284
Over 5 years	3,966
Total	¥ 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, 2019
Total minimum lease payments	¥ 8,300

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18. 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, 2019	As of March 31, 2020
Financial assets at amortized cost		
Loan receivables	¥ 42,793	¥ 25,923
Others	2,917	2,551
Financial assets at fair value through profit or loss		
Derivative assets	—	—
Financial assets at fair value through other comprehensive income		
Equity securities, etc.	72,708	199,165
Bonds	—	2,001
Total	¥ 118,418	229,640
Other financial assets (non-current)	74,668	200,923
Other financial assets (current)	43,750	28,717
Total	¥ 118,418	¥ 229,640

(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, 2019	As of March 31, 2020
Roivant Sciences Ltd.	¥ —	¥ 142,650
JCR Pharmaceuticals Co., Ltd.	5,542	8,007
Medipal Holdings Corporation	8,514	6,538
Ono Pharmaceutical Co., Ltd.	3,611	4,139
Suzuken Co., Ltd.	5,925	3,637
Alfresa Holdings Corporation	5,170	3,305
SanBio Company Limited	8,055	3,272
Mochida Pharmaceutical co., Ltd.	3,076	2,258
HEALIOS K.K..	2,580	2,261
Forest Holdings, Inc.	1,893	1,894
Others	28,342	21,204
Total	¥ 72,708	¥ 199,165

2. Others

The dividend income derived from the financial assets measured at fair value through other comprehensive income held by the Group are ¥1,156 million and ¥1,123 million for the years ended March 31, 2019 and 2020, 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, 2019 and 2020 are as follows:

	Millions of yen	
	Year ended March 31, 2019	Year ended March 31, 2020
Fair value at the time of disposal	¥ —	¥ 1,608
Accumulated gains (losses)	—	1,288
Dividend income	—	—

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 ¥913 million for the year ended March 31, 2020. There was 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 (¥3,070 million) for the year ended March 31, 2020, are reclassified from other components of equity to retained earnings. There was no such reclassification for the year ended March 31, 2019.

19. Inventories

The details of Inventories are as follows:

	Millions of yen	
	As of March 31, 2019	As of March 31, 2020
Merchandise and finished goods	¥ 53,961	¥ 64,683
Work-in-process	1,098	2,284
Raw materials and supplies	11,830	12,401
Total	¥ 66,889	¥ 79,368

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 ¥1,665 million and ¥2,985 million for the years ended March 31, 2019 and 2020, respectively.

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20. 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, 2019	As of March 31, 2020
Financial assets measured at amortized cost		
Accounts receivable and notes receivable	¥ 115,250	¥ 128,478
Other receivables	2,701	5,123
Contract assets	810	970
Allowance for credit losses	(1)	(80)
Total	¥ 118,760	¥ 134,491
Trade and other receivables (non-current)	—	—
Trade and other receivables (current)	118,760	134,491
Total	¥ 118,760	¥ 134,491

(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 29. Financial Instruments.

21. Cash and Cash Equivalents

The details of cash and cash equivalents are as follows:

	Millions of yen	
	As of March 31, 2019	As of March 31, 2020
Financial assets measured at amortized cost		
Cash and deposits	¥ 96,342	¥ 88,513
Short-term investments (cash equivalents)	40,954	13,195
Total	¥ 137,296	¥ 101,708

22. Borrowings

(1) Details of Borrowings

The details of Borrowings are as follows:

	Millions of yen			
	As of March 31, 2019	As of March 31, 2020	Average interest rate	Repayment due date
Long-term borrowings (other than current portion)	¥ 27,980	¥ 25,020	0.18%	June 2021~ March 2023
Current portion of long-term borrowings	2,960	2,960	0.20%	—
Short-term borrowings	—	270,000	0.48%	—
Total	¥ 30,940	¥ 297,980	—	—
Borrowings (non-current)	27,980	25,020	—	—
Borrowings (current)	2,960	272,960	—	—
Total	¥ 30,940	¥ 297,980	—	—

(Note) The average interest rate is the weighted average interest rate calculated based on the balance of the borrowings as of March 31, 2020.

(2) 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 liabilities	Total
Balance as of April 1, 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 lease 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
Balance as of March 31, 2019	—	30,940	—	2,043	32,983
Cash flows provided by financing activities	270,000	(19,623)	—	(4,837)	245,540
Other changes					
Changes in accounting policies	—	—	—	15,315	15,315
Additions due to acquisition of right-of-use assets	—	—	—	2,407	2,407
Acquisitions through business combinations	—	16,742	—	2,659	19,401
Interest expenses	336	54	—	261	651
Payment of interests	(330)	(951)	—	(245)	(1,526)
Effect of foreign currency translation differences	(2)	(149)	—	(224)	(375)
Others	—	967	—	(84)	883
Balance as of March 31, 2020	¥ 270,004	¥ 27,980	¥ —	¥ 17,295	¥ 315,279

23. Trade and Other Payables

The details of trade and other payables are as follows:

Millions of yen

	As of March 31, 2019	As of March 31, 2020
Financial liabilities measured at amortized cost		
Accounts payable and notes payables	¥ 15,498	¥ 25,640
Other payables	33,740	36,611
Total	¥ 49,238	¥ 62,251
Trade and other payables (non-current)	—	—
Trade and other payables (current)	49,238	62,251
Total	¥ 49,238	¥ 62,251

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24. Other Financial Liabilities

The details of other financial liabilities are as follows:

	Millions of yen	
	As of March 31, 2019	As of March 31, 2020
Financial liabilities at amortized cost		
Deposit received	¥ 3,712	¥ 3,906
Others	1,854	2,754
Financial liabilities at fair value through profit or loss		
Contingent considerations	81,352	31,228
Others	99	—
Financial liabilities at fair value through other comprehensive income		
Derivative liabilities	—	45
Lease liabilities	2,043	17,279
Total	¥ 89,060	¥ 55,212
Other financial liabilities (non-current)	80,387	41,306
Other financial liabilities (current)	8,673	13,906
Total	¥ 89,060	¥ 55,212

25. Provisions

(1) Movements of provisions

The movement of provisions is as follows:
Year ended March 31, 2020

	Millions of yen		
	Reserve for sales returns	Reserve for sales rebates	Total
Balance at the beginning of the year	¥ 9,604	¥ 82,572	¥ 92,176
Increase	3,592	73,255	76,847
Decrease (utilization)	(1,930)	(71,722)	(73,652)
Decrease (reversal)	(1,957)	(6,942)	(8,899)
Foreign currency translation differences	(189)	(1,639)	(1,828)
Balance at the end of the year	9,120	75,524	84,644
Provision (non-current)	—	—	—
Provision (current)	9,120	75,524	84,644
Total	¥ 9,120	¥ 75,524	¥ 84,644

(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.

26. 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, 2019	As of March 31, 2020
Present value of defined benefit obligations	¥ 102,007	¥ 99,931
Fair value of the plan assets (including retirement benefit trusts)	78,394	76,061
Net defined benefit (assets) liabilities	23,613	23,870
Retirement benefit liabilities	23,613	23,870
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, 2019	Year ended March 31, 2020
Balance at beginning of the year	¥ 101,380	¥ 102,007
Current service cost	3,406	3,444
Interest expense	727	599
Remeasurement of net defined benefit liability (asset)		
Changes in demographic assumptions	(38)	(529)
Changes in financial assumptions	2,255	1,362
Experience adjustments	(371)	(2,591)
Benefits paid	(5,777)	(4,933)
Foreign currency translation differences	20	(12)
Others	405	584
Balance at end of the year	¥ 102,007	¥ 99,931

(Note) The weighted average number of payment years of defined benefit obligations are 16.7 years and 16.2 years as of March 31, 2019 and 2020, 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, 2019	Year ended March 31, 2020
Balance at beginning of the year	¥ 80,680	¥ 78,394
Interest income	587	506
Benefits paid	(4,182)	(3,505)
Contributions by the employer	2,470	2,356
Remeasurement of defined benefit plans		
Return on plan assets	(1,161)	(1,690)
Others	—	—
Balance at end of the year	¥ 78,394	¥ 76,061

(Note) The Group is expected to pay contributions amounting to ¥2,355 million in the year ending March 31, 2021.

4. Components of plan assets

The details of plan assets by category are as follows:

	Millions of yen					
	As of March 31, 2019			As of March 31, 2020		
	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	¥ 13,233	¥ —	¥ 13,233	¥ 10,863	¥ —	¥ 10,863
Debt securities	40,777	—	40,777	37,002	—	37,002
General accounts of life insurance companies	—	8,852	8,852	—	8,965	8,965
Cash and cash equivalents	2,220	—	2,220	5,082	—	5,082
Others	—	13,312	13,312	—	14,149	14,149
Total	¥ 56,230	¥ 22,164	¥ 78,394	¥ 52,947	¥ 23,114	¥ 76,061

(Note) The retirement benefit trusts set for defined benefit pension plans consist of 7.5% and 6.2% in the total plan assets as of March 31, 2019 and 2020 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, 2019	As of March 31, 2020
Discount rate (%)	0.6	0.6

6. Sensitivity analysis

The effects of changes in the significant actuarial assumptions on the defined benefit obligations as of March 31, 2019 and 2020 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, 2019	As of March 31, 2020
In case that the discount rate increases by 0.5%	¥ (7,225)	¥ (6,877)
In case that the discount rate decreases by 0.5%	¥ 6,934	¥ 7,217

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 ¥2,373 million and ¥2,473 million for the years ended March 31, 2019 and 2020, respectively.

(4) Other Employee benefit expenses

The employee benefit expenses for the years ended March 31, 2019 and 2020 are as follows:

	Millions of yen	
	Year ended March 31, 2019	Year ended March 31, 2020
Salaries	¥ 65,670	¥ 70,150
Bonuses	20,283	21,748
Retirement benefit expenses	7,005	7,050
Business structure improvement expenses	3,007	—
Others	12,891	13,121
Total	¥ 108,856	¥ 112,069

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27. Share-based payments

Myovant Sciences Ltd. and Urovant Sciences Ltd., the Company's consolidated subsidiaries, have introduced Stock Compensation Plans for its directors and employees and granted stock options to them.

1. Stock Option Plans

Stock options that Myovant Sciences Ltd. and Urovant Sciences Ltd. have issued are equity-settled share-based compensation and the vesting conditions are mainly based on service period.

Information related to stock options of Myovant Sciences Ltd. and Urovant Sciences Ltd. for the year ended March 31, 2020 is as follows:

(i) Myovant Sciences Ltd.

	Number of stock options (shares)	Weighted average exercise price (USD)	Weighted average remaining contractual years (year)
Date of acquisition			
Outstanding balance as of December 27, 2019	7,744,257	\$ 9.20	8.29
Granted	223,500	\$ 10.63	—
Exercised	(43,549)	\$ 6.30	—
Forfeited	(200,906)	\$ 9.19	—
Outstanding balance as of March 31, 2020	7,723,302	\$ 9.25	8.08
Exercisable balance as of March 31, 2020	3,009,080	\$ 8.13	7.30

(Note) 1. The weighted average share prices at the time of exercising is \$11.97.

2. The range of exercise prices for outstanding as of March 31, 2020 is from \$2.38 to \$26.17.

The Black-Scholes model was used for the purpose of valuation of the fair value of the stock options. As for the granted stock options during the year ended March 31, 2020, the assumptions used for the Black-Scholes model are as follows:

	Year ended March 31, 2020
Expected weighted average fair value	\$ 6.92
Expected weighted average share price	\$11.42
Expected exercise price	\$10.63
Expected volatility	73.0%
Expected stock option period	6.2 years
Expected dividends	—
Risk-free interest rate	1.23%

(Note) 1. The estimate of expected volatility is based on the historical volatility of Myovant Sciences Ltd., and similar listed companies that and comparable with Myovant Sciences Ltd., corresponding to the expected remaining period of stock options.

2. The assumptions used for measuring the fair value of the stock options granted after the date of acquisition of Myovant Sciences Ltd. are described as above.

(ii) Urovant Sciences Ltd.

	Number of stock options (shares)	Weighted average exercise price (USD)	Weighted average remaining contractual years (year)
Date of acquisition			
Outstanding balance as of December 27, 2019	4,358,720	\$6.63	8.58
Granted	45,700	\$9.54	—
Exercised	(270,320)	\$4.51	—
Outstanding balance as of March 31, 2020	4,134,100	\$6.85	8.38
Exercisable balance as of March 31, 2020	3,875,300	\$6.85	8.29

(Note) 1. The weighted average share price at the time of exercising is \$13.06.

2. The range of exercise prices for outstanding as of March 31, 2020 is from \$3.64 to \$15.66.

The Black-Scholes model was used for the purpose of valuation of the fair value of the stock options. As for the granted stock option during the year ended March 31, 2020, the assumptions used for the Black-Scholes model are as follows:

	Year ended March 31, 2020
Expected weighted average fair value	\$ 5.99
Expected weighted average share price	\$12.99
Expected exercise price	\$ 9.54
Expected volatility	69.8%
Expected stock option period	6.1 years
Expected dividends	—
Risk-free interest rate	1.58%

(Note) 1. The estimate of expected volatility is based on the historical volatility of Urovant Sciences Ltd., and similar listed companies that are comparable with Urovant Sciences Ltd., corresponding to the expected remaining period of stock options.

2. The assumptions used for measuring the fair value of the stock options granted after the date of acquisition of Urovant Sciences Ltd. are described as above.

2. Stock Compensation Expenses

Stock compensation expenses recorded in the Consolidated Statement of Profit or Loss were as follows:

	Millions of yen	
	Year ended March 31, 2019	Year ended March 31, 2020
Selling, general and administrative expenses	¥ —	¥ 984
Research and development expenses	—	295
Total	¥ —	¥ 1,279

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28. 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, 2019	Year ended March 31, 2020
Number of shares authorized	1,500,000	1,500,000
Number of issued shares		
Balance at the beginning of the year	397,900	397,900
Changes during the year	—	—
Balance at the end of the year	397,900	397,900

(Note) All the shares issued by the Company are ordinary shares with no par value which have no limitations on any rights. The issued shares are fully paid.

(2) Treasury shares

The changes of number of treasury shares are as follows:

	Thousands of shares	
	Year ended March 31, 2019	Year ended March 31, 2020
Balance at the beginning of the year	601	603
Changes during the year	2	2
Balance at the end of the year	603	605

(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, 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

(ii) For the year ended March 31, 2020

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
Meeting of the Board of directors (October 28, 2019)	Ordinary share	¥ 5,562	¥ 14.00	September 30, 2019	December 2, 2019

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, 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

(ii) For the year ended March 31, 2020

Date of resolution	Type of share	Total dividend amount (Millions of yen)	Dividend amount per share (Yen)	Declaration date	Effective date of distribution
Annual shareholders meeting (June 23, 2020)	Ordinary share	¥ 5,562	¥ 14.00	March 31, 2020	June 24, 2020

29. 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.

Notes to Consolidated Financial Statements

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries
Years Ended March 31, 2020 and 2019

(2) Overview of financial risk management

Risk management policy

In order to reduce financial risks (such as credit risk, liquidity risk, and market risks, etc.) arising from business operations, the Group performs risk management. Derivatives are used to mitigate part of such risks and are not used for speculative purposes.

(3) Credit risk

1. Summary

Credit risk is the risk of financial loss to the Group if a customer or a counterparty of financial instrument fails to meet its contractual obligations. It mainly arises from the debtors, such as trade receivables due from the Group's customers.

As for the customers' credit risk arising from trade receivables and etc., the Group monitors the status of overdue balances, reviews outstanding balances of each customer according to the Group's internal credit management policies and assesses the credibility of major customers on a regular basis in order to reduce credit risks.

2. Maximum credit risk exposures

The maximum exposures related to the credit risk of financial assets held by the Group are the carrying amount of financial assets presented in the Consolidated Statements of Financial Position.

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 difficulty 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:

(i) 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	¥ —

(ii) As of March 31, 2020

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	¥ 297,980	¥ 299,050	¥ 273,973	¥ 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, 2019	As of March 31, 2020
Receivables	\$ 1,475,530	\$ 1,569,214
Payables	102,848	92,659
Net exposures of the Consolidated Statement of Financial Position	1,372,682	1,476,555
Forward foreign exchange contracts	(70,520)	—
Net exposures	\$ 1,302,162	\$ 1,476,555

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.

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Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries
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(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 ¥5,016 million and ¥5,577 million as of March 31, 2019 and 2020, 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

A part of interest-bearing debts held by the Group are variable interest rates. The impact of interest rate risk on the Group's net profit or loss is immaterial because part of its variable interest rates is less than 0.1% as of March 31, 2020. 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, 2019		As of March 31, 2020	
	Carrying amount	Fair value	Carrying amount	Fair value
Financial liabilities at amortized cost				
Borrowings	¥ 30,940	¥ 30,956	¥ 297,980	¥ 297,985

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, 2019 and 2020.

(i) 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

(ii) As of March 31, 2020

	Millions of yen			
	Level 1	Level 2	Level 3	Total
Financial assets at fair value through other comprehensive income				
Investment securities, etc.	43,514	—	155,651	199,165
Bonds	1,235	766	—	2,001
Total	¥ 44,749	¥ 766	¥ 155,651	¥ 201,166
Financial liabilities at fair value through profit or loss				
Contingent consideration	—	—	31,228	31,228
Financial liabilities at fair value through other comprehensive income				
Derivative liabilities	—	45	—	45
Total	¥ —	¥ 45	¥ 31,228	¥ 31,273

Notes to Consolidated Financial Statements

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries
Years Ended March 31, 2020 and 2019

The movement of the financial instruments of which fair value is classified as Level 3 is as follows:

(i) Financial assets

	Millions of yen	
	Year ended March 31, 2019	Year ended March 31, 2020
Balance at the beginning of the year	¥ 13,392	¥ 16,942
Purchase	2,501	112,090
Changes in financial assets at fair value through other comprehensive income	1,049	27,640
Sales/settlement	—	(668)
Others	—	(353)
Balance at the end of the year	¥ 16,942	¥ 155,651

(ii) Financial liabilities

	Millions of yen	
	Year ended March 31, 2019	Year ended March 31, 2020
Balance at the beginning of the year	¥ 86,616	¥ 81,352
Changes in fair value of contingent consideration (Note)	(9,128)	(48,474)
Foreign currency translation differences	3,864	(1,650)
Balance at the end of the year	¥ 81,352	¥ 31,228

(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 14.1%-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 \$225 million (¥18,958 million) has been paid till March 31, 2020, and it is possible to pay a maximum amount of \$245

million (¥26,658 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 \$1,145 million (¥124,587 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 \$189 million (¥17,800 million) has been paid till March 31, 2020, and it is possible to pay a maximum amount of \$210 million (¥22,850 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 \$195 million (¥22,165 million) has been paid till March 31, 2020, and it is possible to pay a maximum amount of \$430 million (¥46,788 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 \$150 million (¥16,322 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 ¥354,645 million (undiscounted) and ¥237,206 million (undiscounted) as of March 31, 2019 and 2020, 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	
		As of March 31, 2019	As of March 31, 2020
Revenue	Increase by 5%	¥ 2,553	¥ 1,088
	Decrease by 5%	(2,220)	(1,088)
Discount rate	Increase by 0.5%	(1,554)	(435)
	Decrease by 0.5%	1,665	326

Notes to Consolidated Financial Statements

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries
Years Ended March 31, 2020 and 2019

30. Capital Expenditure Commitments

Capital expenditure commitments of acquisition of assets are as follows:

	Millions of yen	
	As of March 31, 2019	As of March 31, 2020
Property, plant and equipment	¥ 3,930	¥ 2,475
Intangible assets	76,508	73,395
Total	¥ 80,438	¥ 75,870

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.

31. Subsidiaries and Associates

(1) The significant subsidiaries and associates

The significant subsidiaries and associates of the Group as of March 31, 2020 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.	\$1 thousand	Holding company (North America) (Note 1)	100%
Sunovion Pharmaceuticals Inc.	Marlborough, MA, U.S.	\$0 thousand	Manufacturing and sales of pharmaceuticals (North America)	100%
Boston Biomedical, Inc. (Note 2)	Cambridge, MA, U.S.	\$0 thousand	R&D in the oncology area (North America)	100%
Tolero Pharmaceuticals, Inc. (Note 2)	Lehi, UT, U.S.	\$0 thousand	R&D in the oncology area (North America)	100%
Sumitovant Biopharma Ltd.	London, U.K.	\$0 thousand	Management of Sumitovant group companies, and formulation and promotion of business strategies, etc. (North America)	100%
Myovant Sciences Ltd.	London, U.K.	\$2 thousand	R&D in the women's health, prostate cancer area (North America)	52.08%
Urovant Sciences Ltd.	London, U.K.	\$1 thousand	R&D in the urology area (North America)	74.96%
Enzyvant Therapeutics Ltd.	London, U.K.	\$0 thousand	R&D in the pediatric rare diseases area (North America)	100%
Altavant Sciences Ltd.	London, U.K.	\$1 thousand	R&D in the respiratory rare diseases area (North America)	100%
Spirovant Sciences Ltd.	Bermuda	\$0 thousand	R&D in the cystic fibrosis gene therapy area (North America)	100%
Sumitomo Pharmaceuticals (Suzhou) Co., Ltd.	Suzhou, Jiangsu, China	\$35,000 thousand	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 Promo Co., Ltd.	Suita, Osaka	¥480 million	Manufacturing and sales of pharmaceuticals, etc. (Japan)	100%

(Note) 1. On April 1, 2020, Sumitomo Dainippon Pharma America, Inc. changed its form of incorporation from a holding company to a company that encompasses some of the functions of our North American subsidiaries (Sunovion Pharmaceuticals Inc., Boston Biomedical, Inc., and Tolero Pharmaceuticals, Inc.), including legal affairs, intellectual property, internal audit, compliance, and financial operations.

2. On July 1, 2020, these two companies merged and changed its name to Sumitomo Dainippon Pharma Oncology, Inc.

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Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries
Years Ended March 31, 2020 and 2019

(2) Subsidiaries with significant non-controlling interests

The summarized financial information for the subsidiaries that the Company recognizes significant non-controlling interest are as follows:

The amounts in the summarized financial information are before inter-company eliminations.

Myovant Sciences Ltd.

1. Non-controlling interests ratio and accumulated amount of non-controlling interests

	Millions of yen	
	As of March 31, 2019	As of March 31, 2020
Non-controlling interests ratio	—	47.9%
Accumulated amount of non-controlling interests	—	75,109

2. Net profit or loss allocated to non-controlling interests and dividends paid to non-controlling interests

	Millions of yen	
	Year ended March 31, 2019	Year ended March 31, 2020
Net profit or loss allocated to non-controlling interests	¥ —	¥ (3,514)
Dividends paid to non-controlling interests	—	—

3. Summarized financial information

(i) Summary of Consolidated Statement of Profit or Loss and Summary of Consolidated Statement of Comprehensive Income

	Millions of yen	
	Year ended March 31, 2019	Year ended March 31, 2020
Revenue	¥ —	¥ —
Net profit (loss)	—	(7,336)
Comprehensive income (loss)	—	(7,425)

(ii) Summary of Consolidated Statement of Financial Position

	Millions of yen	
	As of March 31, 2019	As of March 31, 2020
Non-current assets	¥ —	¥ 177,260
Current assets	—	9,565
Total assets	—	186,825
Non-current liabilities	—	28,747
Current liabilities	—	10,004
Total liabilities	—	38,751
Total equity	—	148,074
Total liabilities and equity	—	186,825

(iii) Summary of Consolidated Statement of Cash Flows

Millions of yen

	Year ended March 31, 2019	Year ended March 31, 2020
Net cash flows from operating activities	¥ —	¥ (2,090)
Net cash flows from investing activities	—	1,362
Net cash flows from financing activities	—	30
Effect of exchange rate changes on cash and cash equivalents	—	—
Net increase (decrease) in cash and cash equivalents	—	(698)
Cash and cash equivalents at end of year	—	8,489

32. 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:

Millions of yen

Type	Company name	Description of transaction	Year ended March 31, 2019		Year ended March 31, 2020	
			Transaction amount	Outstanding balance	Transaction amount	Outstanding balance
Parent company	Sumitomo Chemical Company, Limited	Lending and collection of funds	¥ 21,050	¥ 42,750	¥ (16,520)	¥ 25,881

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, 2019	Year ended March 31, 2020
Basic remuneration and bonus	¥ 455	¥ 465

Notes to Consolidated Financial Statements

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries
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33. Business Combinations and Acquisition of Non-Controlling Interests

(Business Combinations through acquisition)

For the fiscal year ended March 31, 2020

(1) Overview of business combinations

1. Sumitovant Biopharma Ltd.

(i) Name of acquired company and business description

Name of acquired company: Sumitovant Biopharma Ltd.

Business description: Holding company

(ii) Percentage of voting rights acquired:

100%

2. Sumitovant Biopharma, Inc.

(i) Name of acquired company and business description

Name of acquired company: Sumitovant Biopharma, Inc.

Business description: Management of group companies, business and sales development, promotion of utilization of healthcare technology platforms and so forth.

(ii) Percentage of voting rights acquired:

100%

3. Myovant Sciences Ltd.

(i) Name of acquired company and business description

Name of acquired company: Myovant Sciences Ltd.

Business description: Research and development of pharmaceutical of relugolix and MVT-602, etc.

(ii) Percentage of voting rights acquired:

50%

4. Urovant Sciences Ltd.

(i) Name of acquired company and business description

Name of acquired company: Urovant Sciences Ltd.

Business description: Research and development of pharmaceutical of vibegron and URO-902, etc.

(ii) Percentage of voting rights acquired:

75%

5. Enzyvant Therapeutics Ltd.

(i) Name of acquired company and business description

Name of acquired company: Enzyvant Therapeutics Ltd.

Business description: Research and development of pharmaceutical of RVT-802 and RVT-801, etc.

(ii) Percentage of voting rights acquired:

100%

6. Altavant Sciences Ltd.

(i) Name of acquired company and business description

Name of acquired company: Altavant Sciences Ltd.

Business description: Research and development of pharmaceutical of rodatristat ethyl, etc.

(ii) Percentage of voting rights acquired:

100%

7. Spirovant Sciences Ltd.

(i) Name of acquired company and business description

Name of acquired company: Spirovant Sciences Ltd.

Business description: Research and development of pharmaceutical of SPIRO-2101 and SPIRO-2102, etc.

(ii) Percentage of voting rights acquired:

100%

(2) Acquisition date

December 27, 2019

(3) Method for gaining control of acquired company

Acquisition of shares by cash consideration

(4) Main reason for business combination

The Company has completed the share transfer procedures and etc. in accordance with the strategic alliance with Roivant Sciences Ltd. (hereafter, "Alliance") as of December 27, 2019.

In order to achieve sustainable growth even after the expiration of the term for market exclusivity of LATUDA® (atypical antipsychotic) in North America, which has been the primary source of the Group's earnings, the Company established "establishment of growth engines" and "building of flexible and efficient organization" as a basic policy in "Mid-term Business Plan 2022" and reshaped business foundation.

Roivant Sciences Ltd. aims at contributing to health by providing innovative medicines and healthcare technologies rapidly to patients through building multiple Vants, which are biopharmaceutical companies focusing on business agility and entrepreneurship. Each Vant conducts research and development and sales efficiently through unique method of talent employment and introduction of technologies.

Under the Alliance, the Company aims for achieving medium-to-long term growth through acquisition of many pipelines including products under development which are expected to launch before FY2022 and anticipated to become blockbuster products in the future, as well as improving R&D productivity of the whole group and accelerating the digital transformation.

Roivant Sciences Ltd. transferred its ownership of share of interests of five subsidiaries (Myovant Sciences Ltd., Urovant Sciences Ltd., Enzyvant Therapeutics Ltd., Altavant Sciences Ltd., and Spirovant Sciences Ltd.) to the new company, Sumitovant Biopharma Ltd. which is established for the Alliance, and the Company has acquired all the shares of Sumitovant Biopharma Ltd.

Sumitovant Biopharma Ltd. and its five subsidiaries have subsidiaries, respectively. These companies including their subsidiaries become consolidated subsidiaries of the Company.

(5) The details of acquisition cost of acquired company and consideration transferred by type

Consideration transferred	Cash	224,555 million yen
Acquisition cost		224,555 million yen

(6) Acquisition-related costs

Acquisition-related costs are ¥3,856 million and recognized in Selling, general and administrative expenses in the Consolidated Statement of Profit or Loss.

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Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries
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(7) The details of fair value of assets acquired and liabilities assumed, non-controlling interests and goodwill

Account	Amount
Non-current Assets	
Intangible assets	¥ 291,643
Other	3,661
Current Assets	
Cash and cash equivalents	18,781
Other	6,172
Non-current liabilities	40,840
Current liabilities	19,307
Net Assets	260,110
Non-controlling interests (Note 2)	107,783
Goodwill (Note 3)	72,228

(Note) 1: The considerations transferred are allocated to assets acquired and liabilities assumed based on the fair values as of acquisition date.

2: Non-controlling interests are measured by multiplying provisional fair value of identifiable net assets of acquired company at acquisition date by percentage of share of interests after business combination, excluding the portion specifically attributable to non-controlling shareholders.

3: The goodwill is mainly constituted by and reflects future excess earning power expected to be generated from future business development. Such goodwill is not deductible for tax purpose.

(8) Cash outflows arising from acquisition of subsidiaries

Account	Amount
Cash consideration	¥ 224,555
Cash and cash equivalents owned by acquired company on acquisition date	18,781
Cash outflows arising from acquisition of subsidiaries	205,774

(9) The impact on the Consolidated Statement of Profit or Loss

1. Revenue and net profit or loss of acquired company after acquisition date recognized in the Consolidated Statement of Profit or Loss for the year ended March 31, 2020.

Revenue	—
Net profit (loss)	(¥16,712 million)

2. The impact on revenue and net profit or loss in the Consolidated Statement of Profit or Loss for the year ended March 31, 2020, assuming the business combination had been conducted at the beginning of the fiscal year ended March 31, 2020. (unaudited information)

Revenue	—
Net profit (loss)	(¥61,053 million)

(Changes in parent company's ownership interest due to acquisition of non-controlling interests)

The Group acquired 2.0% of the shares of Myovant Sciences Ltd. to strengthen the relationship between the Group and Myovant Sciences Ltd. additionally after the acquisition of all the shares of Sumitovant Biopharma Ltd. for the year ended March 31, 2020. As a result, capital surplus was decreased by ¥1,103 million.

34. Subsequent Events

There are no significant subsequent events.

Independent Auditor's Report

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

Opinion

We have audited the accompanying consolidated financial statements of statement of Sumitomo Dainippon Pharma Co., Ltd. ("the Company") and its consolidated subsidiaries (collectively referred to as "the Group"), 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, 2020, and a summary of significant accounting policies and other explanatory information.

In our opinion, the accompanying consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Group as at March 31, 2020, and its consolidated financial performance and its consolidated cash flows for the year then ended in accordance with International Financial Reporting Standards (IFRS).

Basis for Opinion

We conducted our audit in accordance with auditing standards generally accepted in Japan. Our responsibilities under those standards are further described in the *Auditor's Responsibilities for the Audit of the Consolidated Financial Statements* section of our report. We are independent of the Group in accordance with the ethical requirements that are relevant to our audit of the consolidated financial statements in Japan, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Responsibilities of Management and Corporate auditors and the board of corporate auditors for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of the consolidated financial statements in accordance with IFRS, 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.

In preparing the consolidated financial statements, management is responsible for assessing the Group's ability to continue as a going concern, disclosing, as applicable, matters related to going concern in accordance with IFRS and using the going concern basis of accounting unless management either intends to liquidate the Group or to cease operations, or has no realistic alternative but to do so.

Corporate auditors and the board of corporate auditors are responsible for overseeing the directors' performance of their duties including the design, implementation and maintenance of the Group's financial reporting process.

Auditor's Responsibilities for the Audit of the Consolidated Financial Statements

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with auditing standards generally accepted in Japan will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

As part of our audit in accordance with auditing standards generally accepted in Japan, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, while the objective of the audit is not to express an opinion on the effectiveness of the Group's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- Conclude on the appropriateness of management's use of the going concern basis of accounting and based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the consolidated financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Group to cease to continue as a going concern.
- Evaluate whether the presentation and disclosures in the consolidated financial statements are in accordance with IFRS, the overall presentation, structure and content of the consolidated financial statements, including the disclosures, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.

We communicate with corporate auditors and the board of corporate auditors regarding, among other matters, the planned scope and timing of the audit, significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide corporate auditors and the board of corporate auditors with a statement that we have complied with relevant ethical requirements regarding independence, and communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

Interest required to be disclosed by the Certified Public Accountants Act of Japan

We do not have any interest in the Group which is required to be disclosed pursuant to the provisions of the Certified Public Accountants Act of Japan

Daisuke Harada

Designated Engagement Partner
Certified Public Accountant

Koji Narumoto

Designated Engagement Partner
Certified Public Accountant

Masato Tateishi

Designated Engagement Partner
Certified Public Accountant

KPMG AZSA LLC

Osaka Office, Japan
June 23, 2020

Notes to the Reader of Independent Auditor's Report:

This is a copy of the Independent Auditor's Report and the original copies are kept separately by the Company and KPMG AZSA LLC.

Shareholder Data

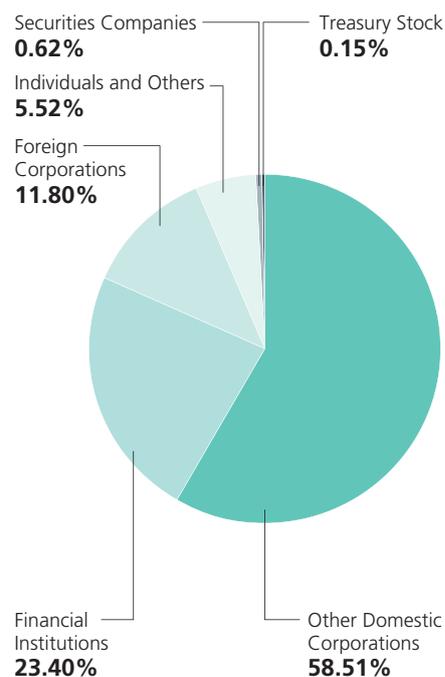
Principal shareholders

(As of March 31, 2020)

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)	29,364	7.39
Inabata & Co., Ltd.	18,555	4.67
Japan Trustee Services Bank, Ltd. (Trust account)	11,742	2.96
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
BNYM SA/NV FOR BNYM GCM CLIENT ACCTS M ILM FE	4,907	1.24
Japan Trustee Services Bank, Ltd. (Trust account 7)	3,676	0.93
Aioi Nissay Dowa Insurance Co., Ltd.	3,104	0.78

Composition of shareholders

(As of March 31, 2020)



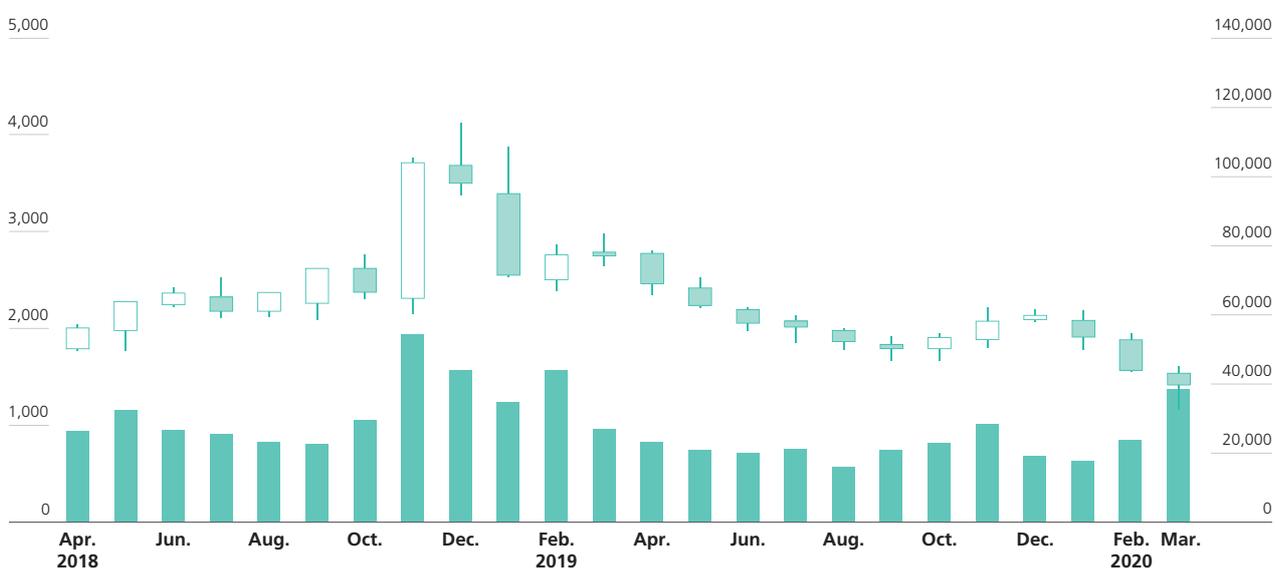
Share price range and trading volume

Share Price

(Yen)

Trading Volume

(Thousands of shares)



External Evaluations of Sumitomo Dainippon Pharma Group on Sustainability

MSCI Japan Empowering Women Index (WIN)

The MSCI Japan Empowering Women Index (WIN) aims to represent the performance of companies that are leading within their GICS® sector groups in terms of promoting and maintaining gender diversity while also meeting certain quality factor criteria. Sumitomo Dainippon Pharma has been independently assessed according to the MSCI Japan Empowering Women Index (WIN) criteria, and has satisfied the requirements to become a constituent of this index in 2017, 2019 and 2020.

2020 CONSTITUENT MSCI JAPAN
EMPOWERING WOMEN INDEX (WIN)

MSCI Japan ESG Select Leaders Index

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

2020 CONSTITUENT MSCI JAPAN
ESG SELECT LEADERS INDEX

FTSE4Good Index Series

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



FTSE Blossom Japan Index

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



SOMPO Sustainability Index

SOMPO Sustainability index is created by the SOMPO Asset Management, and is used in SRI (socially responsible investment) fund for pension funds or institutional investors to invest widely in companies with the high ESG (environment, society, governance) evaluation ratings. Sumitomo Dainippon Pharma has been independently assessed according to SOMPO Sustainability index criteria, and has continuously satisfied the requirements to become a constituent of this index since 2017.



SUSTAINA ESG AWARD

SUSTAINA ESG AWARD is established by SUSTAINA JAPAN in order to celebrate and empower private companies that proactively implement their ESG (Environment, Social, and Governance) management. Based on the original ESG assessment metrics processed by AI, additionally combined with financial evaluation, top 100 ranked companies are selected as ESG Management Leading Companies. In fiscal 2019, Sumitomo Dainippon Pharma was selected as one of the ESG Management Leading Companies and received a Bronze Class award as one of the top 51 to 100 companies selected.





Sumitomo Dainippon
Pharma

2020 CONSTITUENT MSCI JAPAN
EMPOWERING WOMEN INDEX (WIN)

2020 CONSTITUENT MSCI JAPAN
ESG SELECT LEADERS INDEX



FTSE4Good



FTSE Blossom
Japan

2020



Sompo Sustainability Index



IR Site

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



CSR Site

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