



## Innovation today, healthier tomorrows

## Integrated Report 2021

Securities Code 4506

Sumitomo Dainippon Pharma Co., Ltd.

### On the Publication of the Integrated Report 2021

Our Corporate Mission embodies our strong desire to provide solutions for the health issues faced by patients and their families. It is our goal to enhance corporate value by solving these issues, and we believe that putting our Corporate Mission into practice is our CSR-based management.

For our CSR-based management, we identified the material issues to address. In June 2021, we established KPIs for measuring our progress toward solving each of the material issues and we explained the KPIs in our Integrated Report 2021.

Usually, we formulate a Mid-term Business Plan as a concrete business plan for solving the material issues. In May 2021, given changes in business conditions involving the strategic alliance with Roivant Sciences Ltd., we revised the goals of the Mid-term Business Plan 2022. We revised the goals in accordance with changes in the circumstances surrounding business, but our aim of being a "Global Specialized Player" in 2033 has not changed. To achieve that, we are building a flexible and efficient organization, promoting digital transformation measures, and aiming to grow with our three focus research areas (Psychiatry & Neurology, Oncology, and Regenerative Medicine/Cell Therapy), our Frontier Business, etc.

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

> Hiroshi Nomura Representative Director, President and Chief Executive Officer



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### 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 a movie introducing Sumitomo Dainippon Pharma and 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).

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#### **Corporate Site** https://www.ds-pharma.com/

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



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

profile/profile/

Integrated

Report 2021

DSP Gallery (Only available in Japanese) Sumitomo Dainippon Pharma

### https://www.ds-pharma.co.jp/

Roots of the company

Fact Book 2021

Fact Book 2021

profile/profile/

Corporate Profile



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

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#### Hope of the company

**CSR** Site

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### **Editorial Policy**

#### Applicable period

This report is based on the results for fiscal 2020 (April 1, 2020 to March 31, 2021). Some of the activities described were conducted in fiscal 2021.

### 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)

### 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 and medical devices (including compounds under development) contained herein is not intended as advertising or as medical advice.

Myovant Sciences Ltd. ("Myovant"), a consolidated subsidiary, is listed on the New York Stock Exchange, and Sumitomo Dainippon Pharma Group owns approximately 53% of the outstanding shares of Myovant. Each of ORGOVYX®, relugolix (including the relugolix combination Tablet) and MVT-602 is owned by Myovant. This material contains information about Myovant, which is based on information disclosed by Myovant. For more information on Myovant, please visit https://www.myovant.com/

(Note) The information in this report is presented on the IFRS core base unless otherwise specified.



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## Growing globally through a merger of two companies

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
- Psychiatry & Neurology Cardiovascular
   Immunology/Inflammation

### Main products

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

### 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
   Inflammation/Immunology/Allergy
- Psychiatry & Neurology
  - Oncology/Infection

### Main products

- Cardiovascular: Therapeutic agent for hypertension and angina pectoris: AMI ODIN®
- Infection: Carbapenem antibiotic MEROPEN<sup>®</sup>
- Oncology: Natural alpha interferon SUMIFERON<sup>®</sup>

1897 Dainippon Pharmaceutical Co., Ltd.

### 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.)



# 2005 2006

2007 2008 2009

### First Mid-term Business Plan Solid Fundamentals

Maximizing synergies from the integration

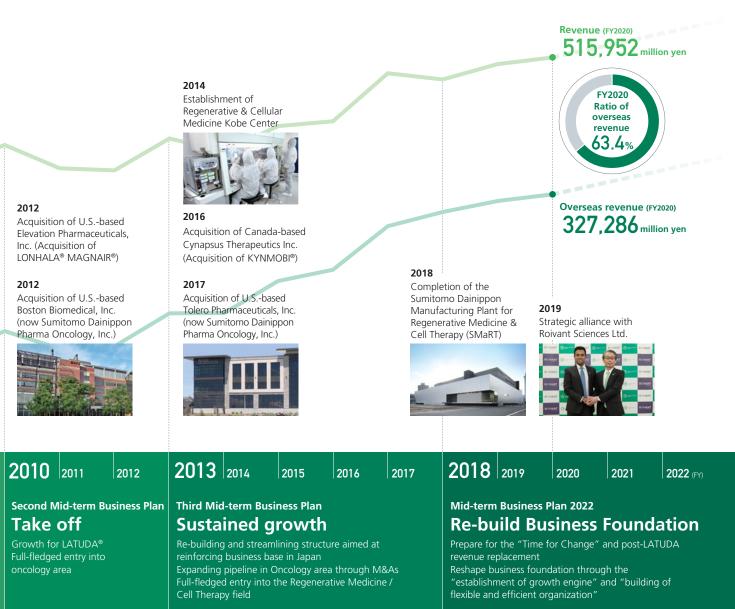
Establishing an overseas sales Psychiatry & Neurology area

→ Please see page 27 for details on Mid-term Business Plan.

**1984** Sumitomo Pharmaceuticals Co., Ltd.

### Trajectory since the establishment of Sumitomo Dainippon Pharma

Since the merger, Sumitomo Dainippon Pharma has actively promoted business globalization. In North America, we have worked on building in-house development and marketing systems for the atypical antipsychotic LATUDA®. As a result of these efforts, LATUDA® has grown into a blockbuster drug with sales of approximately ¥200.0 billion, and Sumitomo Dainippon Pharma has become a global company with an overseas revenue ratio exceeding 60% in fiscal 2020. In research and development, which is the core of our business, in addition to the Psychiatry & Neurology area, we entered the Oncology area full-scale in 2011. We have also been working on the Regenerative Medicine/Cell Therapy field as a new business sector since 2013, well ahead of our competitors. In recent years, we have continued to take on challenges with the aim of providing innovative and valuable pharmaceuticals in any day and age not only to people in Japan but also around the world, such as our frontier business in pursuit of creating healthcare solutions utilizing digital and other technologies.



# For the betterment of healthcare and fuller lives of people worldwide

### Our Mission



The Corporate Mission defines our commitment to society, while the Management Mission states the goals of management, considering relationships with our stakeholders.

The Corporate Mission encapsulates the CSR (corporate social responsibility) that our company needs to fulfill; we define the practice of the Corporate Mission as "CSR-Based Management" and make it our utmost priority.

### **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**

The Declaration of Conduct is a set of concrete guidelines for implementation of our missions. All executives and employees not only comply with all laws and regulations, but also follow this Declaration of Conduct in carrying out corporate activities with a commitment to becoming a company with a strong presence that is trusted by society.

- 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.

Please see this link for more details about our corporate philosophy. https://www.ds-pharma.com/profile/principles/

### **Corporate Culture**

## Fostering an organizational culture characterized by unrelenting efforts instead of satisfaction with the status on a corporate culture of diligence and integrity

### Our perception of corporate culture

Sumitomo Dainippon Pharma, which was created through the merger of Dainippon Pharmaceutical Co., Ltd. and Sumitomo Pharmaceuticals Co., Ltd. in October 2005, started its journey with a commitment to providing innovative and valuable pharmaceuticals for people not only in Japan, but also worldwide.

The merger was a major decision to ensure our ability to continue thriving in the pharmaceutical industry, and we focused on a fusion and harmony of minds to point the employees of both companies in the same direction and achieve synergies as quickly as possible. The management team and employees of the time worked together to promote business as the new Sumitomo Dainippon Pharma rather than as the former Dainippon Pharmaceutical and the former Sumitomo Pharmaceuticals. As a result, we have recognized we were able to unite as a new company quickly and nurture a corporate culture in which the positive elements that both companies possessed before the merger are even more pronounced, namely, diligence, integrity, respect for others, and trust.

Our basic strategy at the time of the merger was "nurturing a corporate culture imbued with an enterprising spirit" in which we identify changes in the environment rapidly and proactively try new things. The many challenges we have tackled since the merger have created the Sumitomo Dainippon Pharma of today, which has transformed itself into a global company.

Going forward, the environment is expected to change more rapidly and be more challenging. We are fostering a corporate culture characterized by unrelenting efforts instead of satisfaction with the status-quo.

Established corporate culture						
Diligence and Integrity	Diligence and Integrity Respect for Others Er					
Corporate culture to be strengthened						
Challenge-Oriented	Transparency	Positive Attitude				

### Instilling CHANTO: delivery of the highest performance

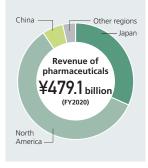
Sumitomo Dainippon Parma is building a flexible and efficient organizational foundation instilled with CHANTO: delivery of the highest performance to achieve the capability to continuously foster and deliver innovation to patients and other customers while transforming our organization in flexible ways to adapt to changes in the world.

We have been promoting the Project CHANTO. Under this initiative, executives have set Conduct Guidelines (=CHANTO) for all employees to challenge themselves to realize the Company's vision and constantly evolve, and we will continue to instill company-wide awareness of CHANTO. Through the initiative, we aim to accomplish both the behavior modifications of each and every employee and the generation of individual and organizational results.

→ Please see page 50 for details about Project CHANTO.

## Strengthening our presence with innovative pharmaceutical products

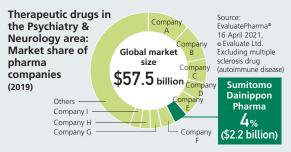
### Pharmaceuticals revenue breakdown by region



### Position in focus areas

### Psychiatry & Neurology area (Global)

Sumitomo Dainippon Pharma has established a leading position in the global market as the company continues to build a unique R&D pipeline in the psychiatric and neurological disorder therapeutic drug market, including atypical antipsychotic LATUDA®, which has global sales of approximately ¥200.0 billion.



### North American market Psychiatry & Neurology area

### LATUDA®

### Revenue: ¥206.5 billion



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Indications Schizophrenia, Bipolar I depression

- Features An atypical antipsychotic with antagonistic effects for dopamine D<sub>2</sub>, serotonin 5-HT2A and serotonin 5-HT7 receptors and also acts as a partial agonist on serotonin 5-HT1A receptors
- Schizophrenia is a chronic disorder with various symptoms, including hallucinations, delusions, social withdrawal, decreased spontaneity, About target cognitive impairment, anxiety, and depression, that makes life, employment, and education difficult. The number of schizophrenia disease patients in the U.S. is approximately 2.4 million.
  - Bipolar disorder is a chronic and serious disease characterized by repeated cycles of manic and depressive episodes. 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. The number of schizophrenia patients in the U.S. is approximately 12.6 million.

APTIOM <sup>®</sup>	
Revenue: ¥25.7 billion Indications Partial-onset seizures (Monotherapy / Combination therapy)	
Features APTIOM <sup>®</sup> is the only exclusively once-dail use as monotherapy or adjunctive therapy	
About • In the U.S., epilepsy is the fourth most p and approximately 2.9 million people an including approximately 460,000 childre	re living with active epilepsy,
KYNMOBI <sup>®</sup> Launched in September 2020	en en en
Revenue: ¥0.2 billion Indications OFF episodes in patients with Parkinson's disease	
Features A sublingual film formulation of apomorp	ohine, a dopamine agonist
About target disease d	n-motor symptoms. By 2030, It is n people in the U.S. and 10

• 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.

### North American market Oncology and other areas

### **ORGOVYX**<sup>®</sup> (relugolix\* monotherapy) Launched in January 2021 Revenue: ¥0.4 billion Indications Advanced prostate cancer Features The first and only oral gonadotropin-releasing hormone (GnRH) receptor antagonist approved in the U.S. About

· Prostate cancer is the second most prevalent form of cancer in men and

- the second leading cause of death due to cancer in men in the U.S. target More than 3 million men diagnosed with prostate cancer are alive in disease
  - the U.S., and approximately 190,000 men were estimated to be newly diagnosed in 2020.

elugolix unched	MBREE® * combination tablet) in June 2021 Is Uterine fibroids	
atures	The first once-daily treatment approved in bleeding associated with uterine fibroids in	
out	An estimated five million women in the uterine fibroids and an estimated three	

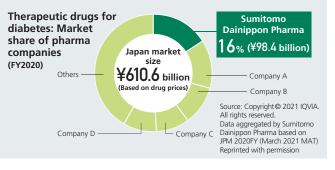
- Ab target treated by current medical therapy and require further treatment. disease
- Relugolix is owned by Myovant Sciences Ltd. Sumitomo Dainippon Pharma Group owns approximately 53% of the outstanding shares of Myovant



 Approximately over 30 million people in the U.S suffer from About bothersome symptoms of OAB, including urinary urgency, urge urinary incontinence, frequent urination, and nocturia which can have a target disease significant impairment on a patient's day-to-day activities.

### **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

TRERIE Revenue: Indication	¥16.2 billion	
Features	Parkinson's disease drug with levodopa-er	nhancing effect
About	• The number of Parkinson's disease patie	ents in Japan is approximately

160,000. Onset often affects those aged 50-65, with the rate of target incidence increasing with age disease

 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.

### LATUDA<sup>®</sup> Launched in June 2020



Indications Schizophrenia and bipolar depression

Features See North American market

Schizophrenia affects approximately 800,000 people in Japan.
Bipolar disorder affects approximately 220,000 people in Japan. About target disease

### **LONASEN®** Tape

Revenue: ¥2.4 billion



Revenue: ¥1.3 billion Indications Schizophrenia

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

• See LATUDA® for Schizophrenia About target disease

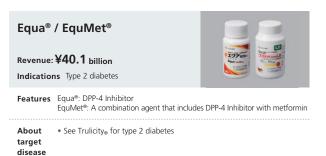
(Note) Revenue for the Japan market is fiscal 2020 performance results based on Invoice price. However, revenue for Trulicity® is NHI price-based sales.

### Japanese market Diabetes area

### **Trulicity**<sub>®</sub> Revenue: ¥33.9 billion Indications Type 2 diabetes Features • Once-weekly glucagon-like peptide-1 (GLP-1) receptor agonist · Single-use self injection pen (Ateos)

About • An estimated 10 million people in Japan have diabetes, with the majority of target them having type 2 diabetes.

 Basic treatment is through exercise and dietary approaches; however, when disease blood glucose levels are not adequately controlled, oral or injectable hypoglycemic agents are administered



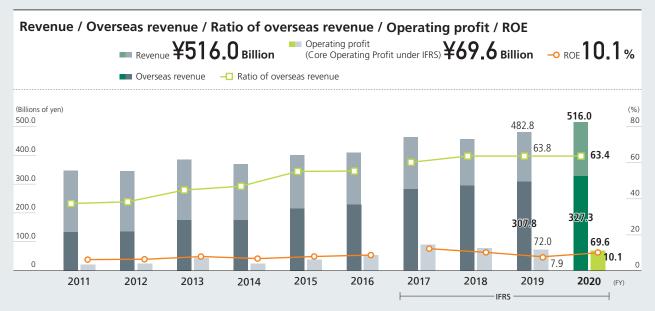
### Chinese market Infectious diseases



Features Standard therapy for severe infections, used in many countries

### **Financial Highlights**

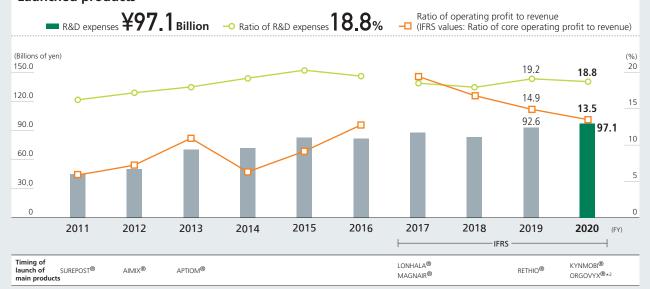
The Sumitomo Dainippon Pharma Group has adopted the International Financial Reporting Standards (IFRS) for preparing its consolidated financial statements from the fiscal year ended March 31, 2018.



The Group's overseas revenue was ¥22.0 billion (ratio of overseas revenue: 8.4%) in fiscal 2006 which is the fiscal year after our merger. Our business foundations in North America was secured by the acquisition of U.S.-based Sepracor Inc. (now Sunovion Pharmaceuticals Inc.) in 2009, together with the launch of LATUDA<sup>®</sup> in the U.S. from February 2011, which grew into a blockbuster product exceeding \$1 billion in sales in fiscal 2015, and overseas revenue has grown steadily to ¥327.3 billion (ratio of overseas revenue: 63.4%) in fiscal 2020. As a result, in fiscal 2017 the Group achieved all-time high operating profit (from fiscal 2017 shown as IFRS core operating profit<sup>\*1</sup> in the graph), and in fiscal 2020 we achieved all-time high revenue.

Our ROE in fiscal 2020 was 10.1%. Our ROE on financial goals for the second half of the 2020s is 10% or greater, despite decreasing to 3% for fiscal 2022, which is the final year of our Mid-term Business Plan 2022 ("the MTBP"), due to reduced profit as a result of increased SG&A expenses.

\*1 Core operating profit is calculated by deducting from operating profit any gains and losses resulting from non-recurring factors that the Group designates.



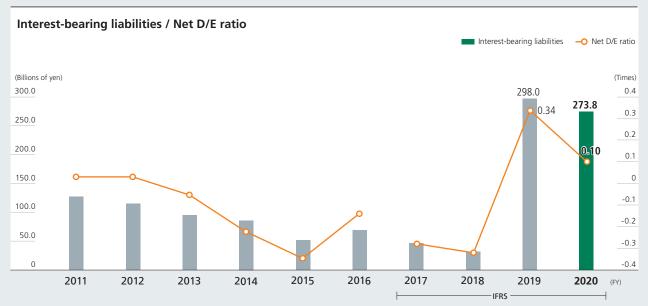
## R&D expenses / Ratio of R&D expenses to revenue / Ratio of operating profit to revenue / Launched products

Research and development investment is essential for the Group to deliver innovative new pharmaceuticals to patients. We proactively invest profit from our business activities with a target ratio of R&D expenses to revenue of up to 20%. As a result, we have launched 15 new drugs since our merger in 2005.

(Note) The graph shows the timing new drugs were first launched, excluding additional indications.

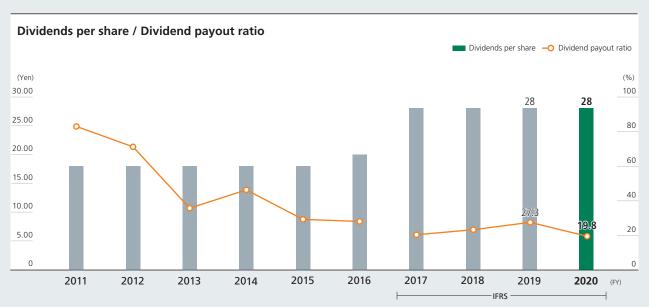
New drugs launched before fiscal 2010 are LATUDA<sup>®</sup> in the U.S., METGLUCO<sup>®</sup>, TRERIEF<sup>®</sup>, MIRIPLA<sup>®</sup>, AmBisome<sup>®</sup>, REPLAGAL<sup>®</sup>, AVAPRO<sup>®</sup>, and LONASEN<sup>®</sup>.

\*2 ORGOVYX® is owned by Myovant Sciences Ltd. Sumitomo Dainippon Pharma Group owns approximately 53% of the outstanding shares of Myovant.



In fiscal 2019, interest-bearing liabilities increased significantly as a result of short-term borrowings of ¥270.0 billion to finance payment of consideration for the strategic alliance with Roivant Sciences Ltd. In fiscal 2020, to maintain financial soundness we issued ¥120.0 billion of hybrid bonds (subordinated bonds) and renewed long-term borrowings of ¥125.0 billion from financial institutions. We will continue to work to strengthen our financial position such as by improving net cash.

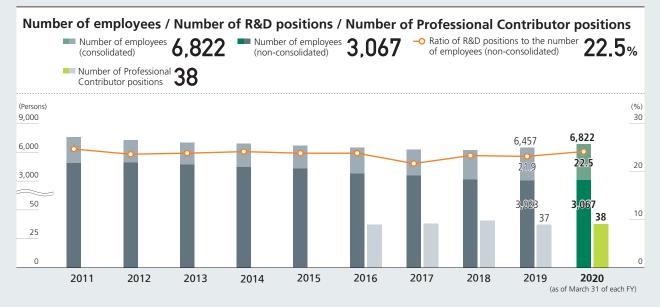
→ Please see page 93 for Financial Policy (Message from the President).



Sumitomo Dainippon Pharma's dividend policy is to maintain consistent dividend payments while also considering a performance-linked dividend hike. We aim for a five-year average dividend payout ratio for the five-year period of the MTBP (FY2018-2022) of 20% or higher.

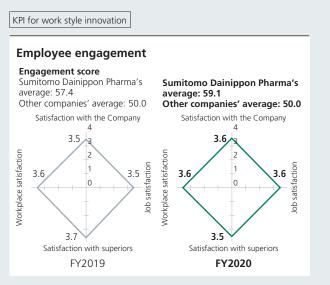
### **Non-Financial Highlights**

All figures are non-consolidated except number of employees (consolidated).



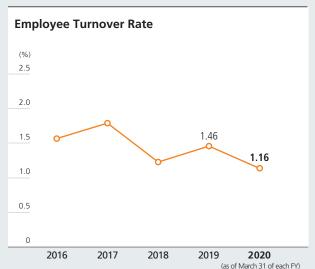
The Company has pursued management efficiency while simultaneously pursuing business expansion and globalization. Moreover, we have maintained a certain ratio of R&D positions to domestic employees, which is a source of value creation. Additionally, in fiscal 2016 we adopted a professional human resources system and established a new position of Professional Contributor (PC). This is the appointment of human resources that produce maximal results through outstanding individual capacity or excellent results based on high level of professionalism.

KPI for work style innovation

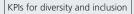


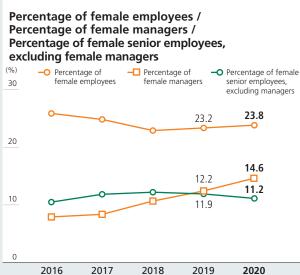
Employee engagement has been set as a key performance indicator (KPI) of work style innovation and we confirm this KPI using employee engagement scores as an indicator. To compare our progress with other companies, we have adopted the Motivation Cloud Service to measure and survey employee satisfaction and expectations since fiscal 2019. The Company has achieved high scores that exceed the averages of other companies in every category.

(Note) Each of the categories—satisfaction with the Company and with superiors, and job and workplace satisfaction—are scored out of five.



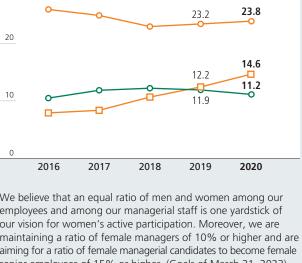
We are aiming to enhance productivity through our promotion of work style innovation. Our key focuses on evaluating productivity are employee work-life balance and sense of fulfilment in work and sense of contribution to the Company. As an indicator to measure these, we are using employee turnover rate as a KPI. The employee turnover rate of employees leaving for personal reasons has been in the 1–1.99% range (less than 2%) for the last five years as a result of enhancing HR systems and creating comfortable working environments.





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. Moreover, we are maintaining a ratio of female managers of 10% or higher and are aiming for a ratio of female managerial candidates to become female senior employees of 15% or higher. (Goals of March 31, 2023)

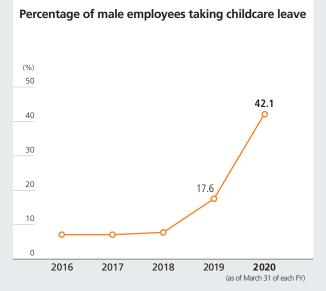
(Note) Ratio of female employees is as of the end of the fiscal year, and the ratio of female managers and the ratio of female senior employees excluding managers are as of April 1 of the following fiscal year.





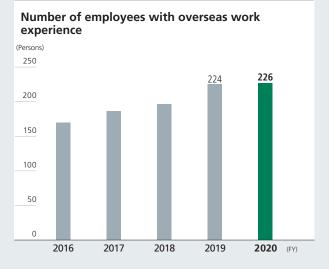
We established the DSP Academy in July 2016 with the aim of providing selected employees involved in management opportunities to acquire the knowledge and so on necessary for senior management positions. Employees with ambition and potential who can be expected to thrive as future executive candidates are selected from various levels-from junior to mid-career, management and supervisory roles. In the five years from fiscal 2016 to 2020, 397 employees took part in the training.

### KPI for diversity and inclusion



We believe a workplace environment with a healthy work-life balance for both males and females is desirable. We are aiming for a workplace environment that is even more conducive to a healthy work-life balance and have set and are working towards an aspirational goal of 100% of male employees taking childcare leave (goal of March 31, 2023). We achieved a ratio of 42.1% in fiscal 2020.

### KPI for training and development of employees



We are promoting initiatives to develop and strengthen human resources who can take on global management roles in future. Every year we are increasing the number of our employees with overseas work experience through measures such as ongoing promotion of HR development initiatives and systematic rotation of employees including to overseas subsidiaries.

(Note) The total number of employees with overseas work experiencestarting from the number out of the total workforce as of March 31, 2016, and for each fiscal year thereafter.

KPI for training and development of employees

# Backcasting to identify future changes in the environment

The changes which are expected in the overall social environment include the advancement of the Fourth Industrial Revolution, demographic aging and the shrinking of the working population, and the relatively lower positioning of Japan and Europe due to the rise of China and other emerging countries.

In the pharmaceutical and healthcare industry to which the Sumitomo Dainippon Pharma Group belongs, further aging society and pressure on healthcare costs are expected to become major issues. In addition, the elucidation of disease mechanisms and the enhancement of preventive and interventional measures may lead to a shift from treatment to prevention and the discovery of new treatment methods for diseases that were previously untreatable.

In the area of pharmaceuticals, the options offered by new modalities such as antibody drugs, nucleic acid drugs, gene therapy, and regenerative medicine and cell therapy are expanding beyond the previous focus on small molecule drugs. In addition, advances in the use of big data and AI across the value chain from drug discovery to marketing are expected to shorten development time, reduce costs, and enhance the probability of success.

In the future, it is expected that pharmaceuticals will continue to be the mainstay of treatment as the solution to unmet medical needs while non-pharmaceutical treatments and preventive medical care using digital technology will become more widely available.

We believe that due to these changes in the environment the pharmaceutical industry will face a Time for Change which will require the establishment of non-conventional new business models. Based on this belief, in April 2019, Sumitomo Dainippon Pharma formulated a new vision and the Mid-term Business Plan 2022 (fiscal 2018 to fiscal 2022) covering the five years starting in fiscal 2018 in order to contribute to solving social issues in a changing healthcare environment.

### Anticipated changes by 2033

### 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





## Identifying and responding to opportunities and risks in the value chain

Sumitomo Dainippon Pharma recognizes opportunities and risks in the value chain, which includes research and development, production and quality control, sales, marketing, corporate regulatory compliance & quality assurance and medical science, and takes measures to reduce risks, including for M&As and alliances. The direction of our responses for each area is as below.

- → Please see page 95 for details on the significant risks that could negatively impact the operating results, cash flow and financial position of Sumitomo Dainippon Pharma Group.
- → Please see page 169 for details on our value chain initiatives

#### Opportunities A Risks Direction of responses

Research and development	<ul> <li>There are high unmet medical needs in the three focus areas (psychiatry &amp; neurology, oncology, and regenerative medicine/cell therapy) with significant impact on healthy life expectancy</li> <li>Open innovation with academia and biotech companies is gaining momentum.</li> <li>Support from regulatory authorities, public institutions, governments and others can be actively utilized.</li> <li>The focus areas of psychiatry &amp; neurology and oncology are areas with a higher degree of uncertainty and 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.</li> <li>If clinical development fails, there are significant losses due to soaring research and development expenses.</li> <li>Non-pharmaceutical disease prevention and treatment methods are emerging (which is an opportunity for Frontier business).</li> <li>We will expand our pipeline by leveraging our competitive technology and know-how and focusing on research and development in our three focus research areas.</li> <li>We will establish a strategic development plan under our global development framework to implement efficient clinical development.</li> <li>We will manage our R&amp;D portfolio appropriately by reviewing research and development policy as is appropriate to match the timing of development stage transitions.</li> </ul>
Production and quality control	<ul> <li>We have built a stable supply structure by strengthening our global supply chains in collaboration with partners in Japan and overseas.</li> <li>The stable supply of products can be impacted by supply chain disruptions caused by natural disasters, such as a major earthquake or flooding, unforeseen accidents, or pandemics.</li> <li>Product quality issues can lead to product recalls, administrative penalties, and loss of social trust.</li> <li>To ensure stable and safe procurement, we use multiple suppliers and consider alternative products and stockpiling. We secure safe inventory of products based on risk.</li> <li>We use audits of our suppliers to check on quality, the environment, and safety, and to request improvements.</li> <li>We have established a global quality assurance system which complies with the laws and regulations of each country.</li> <li>We are making efforts to prevent the occurrence of counterfeit pharmaceuticals.</li> </ul>
Sales and marketing	<ul> <li>Unmet medical needs are increasing due to the aging of the population and responses to rare diseases.</li> <li>Treatment opportunities are growing to meet the need for early detection and prevention.</li> <li>There is a global policy trend to control drug prices to reduce healthcare costs.</li> <li>Changes in the competitive environment, such as the emergence of major competing products, could lead to delays in market penetration and decrease in revenue.</li> <li>We will expand our pipeline to enable contribution to revenue at an early stage.</li> <li>We will commercialize healthcare solutions that provide new value to society with a focus on areas where synergies with our pharmaceutical business are expected.</li> </ul>
Corporate Regulatory Compliance & Quality Assurance / Medical Science	<ul> <li>We can identify unmet medical needs by collecting information from patients, their families, and healthcare professionals.</li> <li>Global standardization of pharmaceutical regulations and quality assurance is making progress.</li> <li>There is increasing use of real world data and digital technology.</li> <li>There can be unexpected adverse reactions after a product is launched.</li> <li>There is an increasingly high level of management due to the diversifying supply chain.</li> <li>The demands of patients and medical institutions are becoming more sophisticated.</li> <li>The level of evidence for medical science information is becoming more diverse and advanced.</li> <li>We evaluate safety information collected from Japan and overseas through centralized global database management.</li> <li>We will plan the necessary measures to ensure the safety and proper use of pharmaceuticals, and implement safety measures in a timely manner.</li> <li>We will create and disseminate information of an advanced scientific level to meet needs.</li> </ul>
M&A and alliance	<ul> <li>We can maximize profit and reduce business risk by partnering on a global basis.</li> <li>We can acquire development pipeline leveraging our solid marketing base.</li> <li>The acquired development pipeline products may be delayed or terminated.</li> <li>Acquired pipeline products may fall short of revenue contribution forecasts after launch.</li> <li>Through strategic investment, we will acquire pipeline in late-stage development which can be expected to contribute to early revenue generation.</li> <li>We will improve profitability by selling products that have reached loss of exclusivity and R&amp;D assets.</li> </ul>

# Utilizing our strengths to create the new drugs patients need

The Corporate Mission and our three strengths (management resources)

### **Business activities and strategy**

### **Corporate Mission**

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

## Our Three Strengths



### **Research & Development**

We possess a rich pipeline, drug discovery capability, leading-edge technology and know-how, broad network related to science, and dedicate efforts mainly in the three focus research areas\*.

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

### **Human Resources**

We have a framework that utilizes the capabilities of individual employees, sincere and excellent human resources, and a corporate culture that promotes a spirit of perseverance and precision.

### **Global Platform**

We have a strong sales network in Japan, North America, and China which forms a base that supports global expansion, and we engage in sales and marketing activities tailored for each region.

## Material issues linked to value

## creation

• Development of Innovative Products and Healthcare Solutions

Psychiatry & Neurology Area	Oncology Area	Regenerative Medicine / Cell Therapy Field
Infectious Diseases Area	Other Areas	Frontier Business

- Contributing to the Development of Science
- Work Style Innovation
- Training and Development of Employees
- Diversity & Inclusion
- Contribution to Global Health
- Initiatives to Improve Access to Medicines And others

**Business activities** 

### Material issues that forms the foundation for business continuity

- Respecting Human Rights
- Corporate Governance
- Risk Management
- Compliance
- Fair and Transparent Corporate Activities
- Corporate Regulatory Compliance, Quality Assurance and Stable Supply
- CSR Procurement
- Health, Safety, and Welfare of Employees
- Environmental Initiatives

Strategic investment aimed at sustained growth (includes research and development investment)

### Value provided to society

### Mid-term Business Plan 2022

### Basic Policy I Establishment of growth engine

- 1.Enhance innovation base with new approaches to drug discovery
- 2.Deliver the highest performance of clinical development
- 3.Pipeline expansion through strategic investment
- 4.Regional strategy centering in Japan, North America and China
- 5.Launch frontier business

### Basic Policy II Building of flexible and efficient organization

- Flexible and efficient organization and operations
- Corporate culture and talent to drive innovation
- Digital transformation

## Patients and their families

Contributing to improving quality of life (QOL)

### **Shareholders**

Stable dividends, increases in dividends linked to improvements in performance

### **Employees**

Personal development, acquiring fulfilment and a sense of happiness through work

Also contributing to achieving the Sustainable Development Goals (SDGs)



Position we aspire to establish in 2033 Global Specialized

## Player

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 pharmaceuticals, 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. Value Creation Strategies

**Message from the President** 

Hiroshi Nomura

Representative Director, President and Chief Executive Officer

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## Establish a growth engine to accelerate the rebuilding of the business foundation for post-LATUDA success in the U.S.\*1

\*1 After the LATUDA® LOE (loss of exclusivity) in the U.S.

### Provide innovative products and healthcare solutions to meet unmet medical needs

In April 2019, Sumitomo Dainippon Pharma announced the Mid-term Business Plan 2022 ("the MTBP"), which runs from fiscal 2018 through to 2022. In formulating the MTBP, we analyzed the changes that could occur in the environment surrounding pharmaceutical companies by 2033. With large changes such as the further aging of society and greater pressure on healthcare costs which are expected going forward, we aim to become a global leader in our three focus areas of research (Psychiatry & Neurology, Oncology, and Regenerative medicine/Cell therapy) and continue contributing to healthcare. Therefore, we need to pursue the sustained growth and enhancement of corporate value by further refining our strengths to appropriately respond to the healthcare needs of society and solve the health-related issues of patients and their families.

As the population ages further, addressing psychiatric and neurological disorders is expected to become an even bigger societal issue and we will continue working on these areas where we can demonstrate our largest strengths. In addition, oncology has already become one of the largest areas in terms of market size, however it has high unmet medical needs where effective treatments have yet to be established. We are also working hard in the Regenerative medicine/Cell therapy field to provide solutions for patients for whom there is no adequate treatment option, as well as treatments for radical cures.

In addition to our own research, we will continue to conduct joint research with external research institutions and academia to address these unresolved medical issues and provide patients with innovative medicines.

In providing healthcare solutions for unmet medical needs, there is no doubt that pharmaceuticals will continue to play an important role, however, we understand that the health-related issues of patients and their families cannot be solved with that alone. In light of this, we are promoting new areas of research, development and commercialization of the Frontier Business that goes beyond drug treatments and transcends the existing boundaries of pharmaceutical companies. The aim of the business is to contribute to the well-being of patients not only in terms of treatment but also in prevention, nursing care, and social reintegration from before they are aware of their illness until they return to their social lives.

In the future, we will continue to focus on the practical applications of new healthcare solutions and provide society with value in addition to pharmaceuticals.

### **Message from the President**

Focus our efforts on maximizing the value of vibegron<sup>\*2</sup> and assisting Myovant in maximizing the value of relugolix<sup>\*3</sup>, advancing ulotaront (SEP-363856) and other compounds to become major products, and pursuing late-stage clinical development areas with global potential

A key focus area of the MTBP is establishing a new growth engine for the Sumitomo Dainippon Pharma Group to replace LATUDA® (lurasidone HCl), which accounts for approximately 40% of our revenue, after LATUDA® LOE (Loss of Exclusivity) in the U.S. While the development of napabucasin, which was considered a strong candidate for post-LATUDA at the time of the announcement of the MTBP, was discontinued in March 2021, the Group acquired or acquired an interest in a pipeline with multiple development compounds to support our sustained growth through a strategic alliance with Roivant Sciences Ltd. (hereinafter, "Roivant") in December 2019. Among the compounds, relugolix and vibegron are potential near-term blockbuster products. This ensures that we have achieved the primary goal of the MTBP which is to establish a post-LATUDA growth engine.

In addition to the launch of relugolix and vibegron as scheduled, the most important task in fiscal 2021 will be to advance the late-stage clinical development of ulotaront, SEP-4199, as well as DSP-7888 and other compounds that are expected, if approved, to contribute to our revenue growth in the medium- to long-term.

In May 2021, we also announced the revision of the financial goals for fiscal 2022 of the MTBP along with changes of business outlook.

The decrease in revenue due to the discontinuation of the development of napabucasin, that was expected to be a post-LATUDA growth driver, and the government drug cost reduction measures in Japan and China will be offset by an increase in sales of new products such as relugolix and vibegron. However, sales-related expenses for these new products and amortization of patent rights are expected to reduce core operating profit. In light of such circumstances, we have revised our financial goals for fiscal 2022 from ¥120 billion in core operating profit, an ROIC of 10%, and an ROE of 12% to ¥60 billion in core operating profit, an ROIC of 3%, and an ROE of 3%. By promoting initiatives for medium- to long-term growth, we aim to achieve an ROE of 10% or higher in the second half of the 2020s. Fiscal 2023 is expected to see a decrease in revenue due to LATUDA® LOE in the U.S., but we will make every effort to minimize the impact of the decline by marketing our mainstay products including vibegron and encouraging Myovant to market relugolix. And we are aiming for an early business recovery and the sustained growth in fiscal 2024 and beyond through the goal to obtain approval of and then launch products under development including ulotaront (for details please see page 29-30).

- \*2 Vibegron is the generic name. In the U.S., it is marketed as GEMTESA® for the treatment of overactive bladder.
- \*3 Relugolix is the generic name. In the U.S., it is marketed by Myovant as ORGOVYX® for the treatment of advanced prostate cancer and as MYFEMBREE® for the treatment of uterine fibroids.
- (Note) Relugolix is owned by Myovant Sciences Ltd. Sumitomo Dainippon Pharma Group owns approximately 53% of the outstanding shares of Myovant.

### CSR-based management through the implementation of the corporate mission Introduced unique KPIs to measure progress toward solving material issues

We define the practice of our Corporate Mission, "To broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide," as CSR-based management. In recent years, corporate sustainability initiatives have attracted attention from a variety of perspectives, including environmental, social, and governance (ESG) practices and the United Nations Sustainable Development Goals (SDGs). I consider that implementing our Corporate Mission diligently will help us receive appropriate ESG evaluations and contribute to achieve the SDGs.

In order to translate our Corporate Mission into concrete action, we identified the material issues (materiality) for CSR-based management in July 2018. Since then, we have regularly reviewed material issues and the Materiality Map (a priority list of the issues to be addressed) based on social changes, the progress of our initiatives, and feedback from our stakeholders. The latest update was made in July 2020.

In addition, in June 2021 we established key performance indicators (KPIs) to manage the progress of each material issue. In developing KPIs, we sought advice from experts through dialogue at meetings including ESG meetings and discussions with board members and members of the Management Committee. We believe these discussions enabled us to establish KPIs that are unique to the Company, rather than those that can be applied to any company, ensuring our achievement of sustained growth and promote CSR-based management. One of our material issues linked to value creation is "Development of innovative products and healthcare solutions." As one of the KPIs to measure the progress of our unique material issues like this, we are considering establishing indicators for the development of ulotaront, a next-generation antipsychotic that would lead to a revolutionary treatment in the psychiatry area, and projects in the Regenerative medicine/Cell therapy field to assess the degree of progress on an ongoing basis.

Foster a corporate culture of creating challenging goals to strengthen the Group's capability to deliver the highest performance ("CHANTO")

Our use of the term materiality covers many topics related to human resources and organization, including work style innovation; diversity and inclusion; training and development of employees; respecting human rights; and the health, safety, and welfare of employees. This is because employees and the organization are actually the driving force for the value creation that we aim for and the most



important foundation that supports our business continuity. Since 2008, we have held a monthly HR Strategy Meeting in which all the directors, some of the executive officers as well as the executive senior directors of divisions discuss human resources development policies, the role of organizations, and personnel systems from a medium- to long-term perspective.

In order to support our growth engine, the MTBP aims to build a flexible and efficient organization instilled with the concept of CHANTO (the capability to deliver the highest performance) through implementation of organizational and operational reforms, and the fostering of a corporate culture and human resources that drive changes in parallel with digital transformation. One of the measures to achieve this goal is to instill the CHANTO concept in our employees. CHANTO provides action guidelines for our employees to set higher goals and work toward becoming a Global Specialized Player. Of course, achieving success in a demanding job is not easy. Given this, it is important not only to improve the abilities of each employee but also to nurture a corporate culture in which employees are willing to set higher goals.

In the research and development of a new drug, no matter how meticulously we plan we may not always achieve the desired results due to various factors such as the potential of compounds. In non-R&D operations, too, sometimes the higher the goal there is a potential greater chance of failure. I think of

### **Message from the President**

failure as being two different types, that is, good failures and bad failures. If an employee set a high goal in line with our Corporate Mission, planned well, worked hard, but failed due to certain circumstances, that is a good failure—a positive failure that will lead to the next step. On the other hand, if the failure is due to an error caused by poor planning, this can be considered as a bad failure.

I would like to foster a corporate culture that encourages successes, as well as good failures that are the result of the best efforts of employees to achieve goals. We must value the work of those employees who try new and innovative approaches. In the future, we will create a system that properly evaluates those who have made meaningful attempts which resulted in good failures and create an environment that encourages employees to challenge themselves to reach higher goals with all their might.

## Accelerate digital transformation to drive behavioral change and to foster a culture of innovation

In the strategic alliance with Roivant we acquired two healthcare technology platforms that supported Roivant's business model— DrugOME and Digital Innovation—and also the associated human resources. We have set digital transformation (DX) as one of the key measures in the MTBP and focused on utilizing it to create



innovative drugs, improve the probability of success, use it in healthcare solutions, and the establishment of efficient operations. The acquisition of Roivant's digital platforms has enabled us to dramatically accelerate the Group's DX initiatives. Currently, a dedicated technology team is working closely with broader business teams to promote the use of the digital infrastructure throughout the Group.

Through the effective use of these infrastructures, we hope to innovate the business processes of the entire company and foster a culture of innovation throughout the Group thereby leading to behavioral changes in our employees. By optimizing workflows with digital technology and improving the digital literacy and data utilization skills of employees, we expect that we can change the work style to be evidence-based, that is, based on solid data not only in R&D but also in sales, administration and other operations, so that we can focus on what humans need to do while we have artificial intelligence (AI) and other digital technologies do what they can. I am convinced that continuous efforts by employees to transform themselves will lead to the strengthening of the Group's ability to deliver its highest performance.

### Promote initiatives to continue our business activities and improve productivity during the global COVID-19 pandemic

The COVID-19 pandemic which began in early 2020 is still having a significant impact around the world. Under these circumstances, the most important thing for us is to continue our usual business activities and fulfill our responsibility to provide a stable supply of pharmaceuticals while safeguarding our employees. At present, we procure most of the raw materials for our pharmaceuticals from Japanese suppliers, but many of those suppliers procure their materials from overseas. We are fortunate that our procurement of the raw materials has not been affected by the pandemic at this point, but we

will review the entire supply chain and update our business continuity plan so that we can continue to fulfill our supply responsibilities in the event of any unforeseen circumstances.

Meanwhile, with restrictions on the movement of people and the holding of large meetings, we have been encouraging our employees to work from home for various tasks while seeking virtual approaches for activities such as the pharmaceutical detailing activities of medical representatives and meetings in each department. While working from home has advantages, such as eliminating the time lost commuting and making more effective use of time, compared with talking face-to-face, it is difficult to have wide ranging and in-depth conversations, and I feel there are things that need to be solved with regard to educating human resources. In the future, I would like to continue to enhance the environment to help our employees improve their skills in working from home so that we can be more creative and productive in our business.

### Revise Basic Environmental Policies to achieve net-zero GHG emissions by fiscal 2050 toward a decarbonized society

Another material issue that is becoming increasingly important is our environmental initiatives. As a pharmaceutical company, we are aware of our responsibility and have been working to reduce our environmental impact in all areas of our business activities. In 2005, we established the Basic Environmental Policies that describe our objectives and initiatives to meet them as guidelines for our environmental activities. Since then, social demands for companies to reduce their environmental impacts have become even more severe as evidenced by the Japanese government's announcement of the 2050 Carbon Neutral Declaration. In order to respond to the increasing social demands, in May 2021 we revised our Basic Environmental Policies.

Under the new policies, we aim to

achieve net-zero greenhouse gas (GHG) emissions (scopes 1 and 2) by fiscal 2050 for realizing a decarbonized society and are working to promote medium- to long-term initiatives to reduce our environmental impact throughout the entire value chain.

## Become Sumitomo Pharma and move toward a new business stage

On April 1, 2022, we will change our trade name from Sumitomo Dainippon Pharma to Sumitomo Pharma with the aim of building a globally accepted Sumitomo brand and moving toward a new business stage.

As our predecessor Dainippon Pharmaceutical was founded in 1897 as Japan's first pharmaceutical company, I am sentimental about seeing the name "Dainippon" disappear from our company name. However, the Company itself has changed significantly since the merger with Sumitomo Pharmaceuticals in 2005, and in order for us to continue growing we must evolve our company into a solution provider for new healthcare issues not only through conventional pharmaceuticals but also through regenerative/cellular medicines and the Frontier Business. Changing our company name to Sumitomo Pharma embraces our determination to advance forward boldly in this new era for the company and society.

The Company will continue to take on the challenge of creating innovative pharmaceuticals and healthcare solutions to contribute to the health and well-being of people, thereby achieving the sustained growth for ourselves. As we prepare well for LATUDA® LOE, we will maximize the value of next-generation blockbuster candidates, strengthen our business foundations, and chart a new growth path. I would like to ask all of our stakeholders for their continued support in the future.

Representative Director, President and Chief Executive Officer

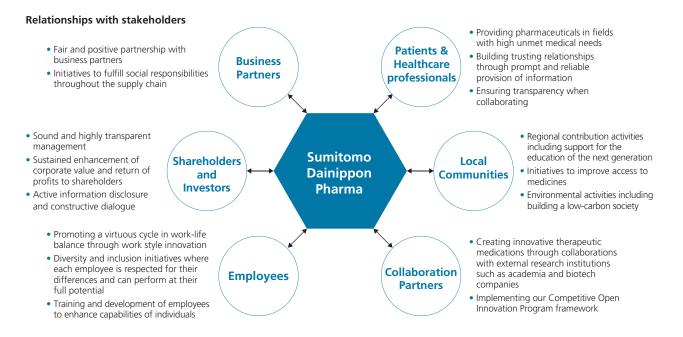
## We define and promote putting into practice our Corporate Mission as CSR-based management

### Our approach to CSR-based management

Sumitomo Dainippon Pharma defines the practice of its Corporate Mission, "To broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide," as CSR-based management. We aspire to implement CSR-based management through developing innovative products and healthcare solutions as well as respecting human rights, maintaining and reinforcing the corporate governance system, promoting work style innovation and diversity & inclusion, strengthening employees training and development, contribution to global health, and taking initiatives to improve access to medicines.

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 8: Decent work and economic growth, Goal 12: Responsible consumption and production, and Goal 17: Partnerships for the goals.

We also believe we need to continue strengthening our relationships by enhancing dialogue with our stakeholders.



### **Our Top Priority Sustainable Development Goals and Targets**

3 GOOD HEALTH AND WELL-BEING	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.
	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.
12 RESOLUTE CONTINUES AND PRODUCTION	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.

8 DECENT WORK AND 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.

PARTINERSINPS FOR THE GOALS

Encourage and promote effective public, public-private and civil society partnerships, building on the experience and resourcing strategies of partnerships.

Please visit the following website to see our initiatives towards achieving various SDG goals. https://www.ds-pharma.com/csr/management/sdgs\_efforts.html

### Materiality

Sumitomo Dainippon Pharma identified the material issues (materiality) of CSR-based management in fiscal 2018. Since then, we have continued to review them based on opinions obtained through stakeholder dialogue. In fiscal 2019, we divided them into material issues linked to value creation, where solving issues is important for our sustained growth, and material issues that form the foundation for business continuity, where solving issues is essential for our business continuity.

In fiscal 2021, we established KPIs to evaluate and analyze the progress of each material issue in addition to the targets that are linked to our business plans and

management issues. We believe sharing of our initiatives-including non-financial information-will help promote greater dialogue with our stakeholders. Moreover, revision of material issues and targets and setting of KPIs are determined following deliberation by the Management Committee and are reported to the Board of Directors.

### Process of determining materiality targets and KPIs (FY2020-2021)

Updating of material issues at Management Committee and		Holding of ESG Meeting (Discussion with	<b>→</b>	Exchange of opinions with experts	<b>→</b>	Discussions of materiality		Determined targets and KPIs following deliberation by	Materiality targets and KPIs
setting of qualitative targets (July 2020)	_	Investors) (December 2020)		Hearings with departments in charge		targets and KPIs	_	Management Committee and reported to the Board of Directors	 were established (June 2021)

Material issues linked to value creation —solving issues is important for our sustained growth

Very High Significance	<ul> <li>Improvement of healthcare infrastructure in developing countries</li> <li>Measures to address falsified medicines</li> </ul>	<ul> <li>Contribution to global health</li> <li>Initiatives to improve access to medicines</li> </ul>	<ul> <li>Development of innovative products and healthcare solutions</li> <li>Contributing to the development of science</li> </ul>	
Societal Sign	• Local community contribution	• Patient support and advocacy	<ul> <li>Work Style Innovation</li> <li>Diversity &amp; inclusion</li> <li>Training and development of employees</li> </ul>	
5 -	High	Importance to Sumitomo Dainippo	on Pharma's Business	Very High

Material issues that form the foundation for business continuity —solving issues is essential for our business continuity

- Respecting human rights
- Compliance
- Corporate governance • Risk management
- Fair and transparent

corporate activities

- CSR procurement • Health, safety, and welfare
- of employees
  - Environmental initiatives
- Corporate regulatory compliance, quality assurance and stable supply

### **CSR-Based Management and Materiality**

### Material issues linked to value creation

Material issues	Targets	KPIs	Page
Development of innovative products and healthcare solutions Contributing to the development of science	<ul> <li>Continuous development of pharmaceuticals in areas with high unmet medical needs</li> <li>Development of healthcare solutions to respond to the future healthcare needs centered on areas where synergies with the pharmaceutical business can be expected</li> </ul>	<ul> <li>Progress on main development pipeline</li> <li>Targets in Psychiatry &amp; Neurology area (ulotaront (SEP-363856): launch in fiscal 2023 (U.S.), SEP-4199: launch in latter half of 2020s)</li> <li>Targets in Oncology area (DSP-7888: launch in fiscal 2024 (Japan and U.S.)</li> <li>Targets in Regenerative Medicine / Cell Therapy field (congenital athymia: launch in fiscal 2021 (U.S.), Parkinson's Disease: launch in fiscal 2023 (Japan), age-related macular degeneration: launch in fiscal 2025 (Japan))</li> <li>Targets for other areas with high unmet medical needs (relugolix: Myovant approval for endometriosis in fiscal 2022 (U.S.), rodatristat ethyl: launch in fiscal 2023-2025 (Japan and U.S.))</li> <li>Targets for Frontier business (commercialization of multiple products (target: launch in fiscal 2023–2025 (Japan and U.S.)))</li> <li>Progress on early-stage development pipeline</li> <li>Number of transitions to Phase 2 and Phase 1 in Psychiatry &amp; Neurology area and Oncology area</li> <li>Progress on development of modalities</li> <li>Work motivation of research &amp; development staff</li> <li>Evaluation score of research &amp; development staff in employee engagement survey</li> </ul>	P.32
Work Style Innovation	<ul> <li>More sophisticated work styles</li> <li>Virtuous cycle in Work-life balance</li> </ul>	Employee engagement     Employee Turnover Rate	P.48
Diversity & inclusion	<ul> <li>Promotion of active participation by female employees</li> <li>Promotion of LGBTQ understanding</li> <li>Promotion of active participation by people with disabilities through appropriate placement</li> </ul>	<ul> <li>Percentage of female managers (maintain at least 10%)</li> <li>Percentage of female senior employees, excluding female managers (15% by April 2023)</li> <li>Percentage of male employees taking childcare leave (100%)</li> <li>Number of participants in e-learning on LGBTQ</li> <li>Number of ALLY activities</li> <li>Average length of employment of employees with disabilities</li> </ul>	P.51
Training and development of employees	<ul> <li>Fostering of leaders and training of globally-minded human resources</li> <li>Fostering a corporate culture that encourages self-disciplined and independent career development</li> </ul>	<ul> <li>Number of participants in selective training</li> <li>Number of employees with overseas work experience</li> <li>Number of cases and applicants utilizing internal job posting system</li> <li>Number of career consultations</li> </ul>	P.50
Patient support and advocacy	<ul> <li>Improving disease-related literacy for patients, their families, and society</li> </ul>	<ul> <li>Activities from patient perspective through healthcare professionals</li> <li>Level of understanding and satisfaction of participants in public lectures</li> <li>Number of support activities through donations and cooperation with patients' associations</li> <li>Dissemination to raise awareness of diseases through our website</li> </ul>	P.66
Local community contribution	<ul> <li>Fulfilling responsibilities and contributing as a member of the community with awareness of harmony with society</li> </ul>	<ul> <li>Number of activities to support the development of the next generation and level of understanding and satisfaction of participants</li> <li>Number of donations for social contribution that lead to resolution of social issues (disasters, people with disabilities, the environment, biodiversity, etc.)</li> <li>Number of charitable activities in local communities</li> </ul>	P.67
Contribution to global health	<ul> <li>Development of drugs to treat malaria and antimicrobial-resistant (AMR) bacterial infections</li> <li>Strengthening of public-private collaboration on countermeasures against AMR and appropriate use of antibiotics</li> <li>Promotion of public awareness-raising activities for health, hygiene, and nutrition</li> </ul>	<ul> <li>Progress of development in infectious diseases area</li> <li>Number of projects</li> <li>Number of products (number of products launched)</li> <li>Number of policy recommendations in infectious diseases area*</li> <li>Number of policy necommendations in infectious</li> </ul>	P.64
Initiatives to improve access to medicines	<ul> <li>Promotion of public awareness-raising activities with the aim of improving medicine-related literacy</li> <li>Response to requests for the development of unapproved and off-label drugs</li> <li>Acceleration of provision of drugs at fair prices</li> </ul>	<ul> <li>Number of programs aiming to improve medicine-related literacy</li> <li>Number of responses to requests for unapproved and off-label drugs</li> <li>Number of policy recommendations by the Company on access to medicines*</li> </ul>	P.64
Improvement of healthcare infrastructure in developing countries	<ul> <li>Support for capacity building of healthcare professionals, development of healthcare networks, etc.</li> <li>Support for development of pharmaceutical regulations and supply chains in collaboration with local governments and international organizations</li> </ul>	<ul> <li>Number of community care volunteers trained through maternal and child health programs in developing countries</li> <li>Number of partnerships working to improve healthcare infrastructure in developing countries</li> </ul>	P.65
Measures to address falsified medicines	<ul> <li>Prevention of falsified medicines and illicit distribution</li> </ul>	_	Webs

\* Disclosure of categories only, not actual figures, etc.

Material issues	Targets	KPIs	Page		
Respecting human rights	<ul> <li>Promotion of respecting human rights throughout all the value chain based on global trends</li> <li>Promotion of initiatives in accordance with the United Nations Guiding Principles on Business and Human Rights</li> </ul>	<ul> <li>Formulation of a basic policy for human rights</li> <li>Promotion of understanding of and action on the basic policy at Group companies</li> <li>Encouragement of respect for human rights by business partners, including suppliers</li> </ul>			
Corporate governance	<ul> <li>Pursuit of highly effective corporate governance</li> <li>Ensuring the independence of management and protecting the interests of minority shareholders</li> </ul>	<ul> <li>Appropriate management and supervision of Group companies</li> <li>Addressing the revised Corporate Governance Code appropriately</li> <li>Implementing evaluation of the effectiveness of the Board of Directors and working on priority issues based on the results of evaluation</li> <li>Conducting appropriate transactions between Group companies with consideration to protecting the interests of minority shareholders</li> </ul>	P.71		
Risk management	<ul> <li>Implementing risk assessment and taking countermeasures</li> <li>Rebuilding of business continuity plans (BCP)</li> <li>Proper information management (management of confidential information, internal information and personal information, Information Technology security)</li> </ul>	<ul> <li>Implementing risk assessment and examining and implementing appropriate countermeasures based on results of assessment</li> <li>Rebuilding, and implementing training and drills of business continuity management (BCM) and business continuity plans (BCPs)</li> <li>Provision of education and training aimed at proper information management</li> <li>Number of serious information leaks and other incidents</li> </ul>	P.82		
Compliance	<ul> <li>Practice of the Declaration of Conduct and Compliance Standards</li> <li>Appropriate operation of compliance promotion system and establishment of rules</li> <li>Improvement in the effectiveness of the whistle-blowing system</li> <li>Ensure exclusion of anti-social forces and prevention of corruption</li> </ul>	<ul> <li>Number of serious compliance violations</li> <li>Implementation of compliance education and training</li> <li>Implementation rate of initiatives to ensure compliance (identification of compliance risk and review of countermeasures)</li> <li>Implementation of compliance awareness surveys</li> <li>Level of awareness and understanding of whistle-blowing system and number of reports</li> </ul>	P.84		
Fair and transparent corporate activities	<ul> <li>Sincere corporate activities contributing to the enhancement of stakeholder engagement</li> </ul>	<ul> <li>Number of stakeholder dialogues</li> <li>Ensuring transparency on relationships with healthcare professionals and patients groups</li> <li>Promotion of appropriate provision of information based on scientific evidence</li> </ul>			
Corporate regulatory compliance, quality assurance and stable supply	<ul> <li>Ensuring strong quality assurance and regulatory affairs as well as data integrity</li> <li>Practice of pharmacovigilance by centralized management of safety information and implementation of timely safety measures</li> <li>Prevention of occurrence of drug-induced suffering</li> <li>Promotion of proper use by provision of appropriate information</li> </ul>	<ul> <li>Implementation of management reviews</li> <li>Responding to inspections and audits</li> <li>Providing education on collection of safety information, quality assurance and drug-induced suffering</li> <li>Integrated management of safety information and early detection of risks</li> <li>Consideration and implementation of revisions to Precautions in package inserts</li> </ul>	Website		
	<ul> <li>Continuation of three Ss (safe operations, sound quality and stable supply)</li> <li>Strengthening of supply chain</li> </ul>	<ul> <li>Number of serious accidents</li> <li>Number of product recalls due to quality issues</li> <li>Rationalization of safety stock standards</li> <li>Rebuilding and strengthening of BCPs</li> <li>Implementation of supplier risk assessments</li> </ul>	Website		
CSR procurement	<ul> <li>Achievement of balanced, fair, and transparent transactions</li> </ul>	<ul> <li>Implementation of supplier surveys (identification of supplier survey targets and implementation of supplier survey)</li> </ul>	Website		
Health, safety, and welfare of employees	<ul> <li>Promotion of health through practice of the declaration of "Health Innovation"</li> <li>Occupational health and safety activities, prevention of occupational accidents</li> </ul>	<ul> <li>Smoking rate of employees (target: -2%/year)</li> <li>Prevention of serious illness (percentage of health checkups for employees covered by specific health guidance (target: 100%), Percentage of health checkups for employees requiring treatment based on instructions of occupational physician (target: 100%)</li> <li>Percentage of employees receiving stress checks (target: 100%)</li> <li>All insured persons and dependents to receive specific health checkups for preventing metabolic syndrome in the over-40s (target: 100%)</li> <li>Work-related accident frequency rate and lost-time injury frequency rate (excluding accidents involving business vehicles)</li> </ul>	Website		
Environmental initiatives	<ul> <li>Building a low carbon society</li> <li>Efficient use of resources (water and waste)</li> <li>Proper information disclosure and responding to TCFD</li> </ul>	<ul> <li>Implementation of measures to achieve fiscal 2030 and fiscal 2050 goals</li> <li>Per-unit energy consumption</li> <li>Recycling rate and final disposal rate of waste</li> <li>Acquisition of third-party assurance for environmental data</li> <li>Promotion of evaluation of risks and opportunities related to climate change and water</li> </ul>	P.59		

### Material issues that form the foundation for business continuity

# Steadily advancing toward realization of the medium- to long-term vision

### 2005 - 2006

### 2007-2009

## Maximizing Synergies from the Integration

### **Strategy Outline**

Based on the philosophy for the integration of "aiming to become a global R&D oriented pharmaceutical company," in Japan, we will look to achieve marketing synergies for the four main products (AMLODIN<sup>®</sup>, GASMOTIN<sup>®</sup>, PRORENAL<sup>®</sup>, and MEROPEN<sup>®</sup>) and new products, and realize cost synergies by narrowing down our strategic areas and effectively utilizing resources and functions. The two companies will also integrate their capital expenditure plans, thereby reducing investments that had been planned separately.

### **Achievements**

After the merger in October 2005, we made steady progress in achieving synergies in the three areas of business, cost, and culture, and we worked to expand our presence with a team of 1,500 MRs that emphasizes improving customer satisfaction as the basis for marketing strategy. We also worked to integrate management of R&D and consolidate sites, completing the integration as of the end of the fiscal year ended March 31, 2007.

### Challenges

It is necessary to clarify the medium- to long-term vision with the aim of maximizing post-integration synergies. In addition, becoming an internationally competitive R&D oriented company and taking measures to expand overseas revenue are important in order to move away from being a business that is centered on Japan.

### Main new products

Japan • Therapeutic agent for systemic fungal infection AmBisome®



### First Mid-term Business Plan Solid Fundamentals

### Strategy Outline

We established a medium- to long-term vision for the next ten years. We will aim to establish a solid foundation of our domestic business, and to expand our own overseas sales organization. In research and development, we will strengthen our drug discovery capabilities and engage in aggressive in-licensing activities aimed at enriching our R&D product pipeline to realize future vision.

### Achievements

We established and expanded our North American marketing base and R&D sites through submission of our own application for approval of LATUDA®, an atypical antipsychotic, in North America, accelerated development of our own sales organization, and acquisition of U.S. pharmaceutical company Sepracor Inc. (currently Sunovion Pharmaceuticals Inc.) In Japan, we introduced a regional headquarters system in the Sales & Marketing Division aimed at developing locally-based marketing and improving profitability.

### Challenges

While we were able to establish the framework for overseas business expansion, including the acquisition of Sepracor in the U.S., we were unable to achieve our profit targets due to a higher-than-expected decline in sales of long-listed products in Japan. In research and development, although we reached the target number for products to be launched during the First Mid-term Business Plan period, we did not achieve good results during the plan period regarding in-licensing of development compounds.

### Main new products

- Japan Fabry disease drug REPLAGAL®
  - Atypical antipsychotic LONASEN<sup>®</sup>
    Therapeutic agent for
  - hypertension AVAPRO®
  - Therapeutic agent for Parkinson's disease TRERIEF®



### 2010-2012

## 2013-2017

## Second Mid-term Business Plan Take Off

### **Strategy Outline**

Under the theme of "Creation and transformation toward a new stage of globalization," the Company set the goals of working to maximize the product value of LATUDA<sup>®</sup>, strengthening profitability in North America, structural reform in the domestic business, expansion into Europe and Asia, and pursuit of management efficiency. For future growth, the Company will aggressively invest in the expansion of its development pipeline on the Psychiatry & Neurology area as a focus area, strategic alliances and in-licensing, and the development and strengthening of human resources.

### Achievements

In Japan, sales of strategic products and new products expanded, and we strengthened marketing capabilities in the Psychiatry & Neurology area, which is a focus area. In North America, sales of LATUDA® grew steadily. We acquired U.S. biotech company Boston Biomedical, Inc. (currently Sumitomo Dainippon Pharma Oncology, Inc.), making a full-scale entry into R&D in the Oncology area, and newly established the DSP Cancer Institute in Japan.

### Challenges

Although sales and profit progressed in line with plans in Japan, the risk of declining revenue from long-listed products increased rapidly, necessitating acceleration in the transformation of our earnings structure. Although sales in North America grew, we did not reach our profit targets due to a variety of factors. In the midst of major changes in our business structure with our full-scale entry in the Oncology area, we faced a shortage of late-stage development compounds.

### Main new products

- 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 • Atypical antipsychotic America LATUDA®



### Third Mid-term Business Plan Sustained Growth

### Strategy Outline

Under the theme of "Quest for further innovation," we will aspire to be a globally competitive R&D oriented company and contribute to medical care through leading edge technologies. We will aim to globally grow businesses through LATUDA® and new products in the Oncology area. In research and development, we will promote exploration of the Regenerative Medicine/Cell Therapy field in addition to the Psychiatry & Neurology area and the Oncology area. We will strengthen the business foundation through a transformation to a leaner corporate structure.

### **Achievements**

Although we achieved growth through significant expansion in sales of LATUDA® in North America, the launch of the oncology business did not proceed according to plan. In research and development, we expanded our pipeline through acquisitions and made progress in R&D in the Regenerative Medicine/Cell Therapy field. We also achieved acceptable results in pursuit of CSR and continuous management efficiency, establishment of a corporate culture that encourages willingness to take on a challenge, and human resource development.

### Challenges

The environment surrounding the pharmaceutical industry is expected to change significantly over the next 15 years. We are facing a "Time for Change" in which the establishment of non-conventional new business models is imperative. Radical reform is needed to move away from a revenue structure dependent on LATUDA® and to achieve sustained growth.

### Main new products

- Japan Therapeutic agent for pruritus REMITCH®
  - (additional indication) Promotion alliance
    - Therapeutic agent for Type 2 Diabetes Trulicity<sub>®</sub> Sales alliance
- North Antiepileptic APTIOM®

America

China • Atypical antipsychotic LONASEN®



# Revision of Mid-term Business Plan 2022 in light of changes in business environment

### **Revision of Mid-term Business Plan 2022**

Sumitomo Dainippon Pharma believes that the pharmaceutical industry is facing a Time for Change when the establishment of non-conventional new business models is imperative to 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. In April 2019, we formulated our Vision and the five-year Mid-term Business Plan 2022 (fiscal 2018 to fiscal 2022) starting in fiscal 2018 based on this belief in order to solve social issues in the changing healthcare area.

Sumitomo Dainippon Pharma set a vision of becoming a global leader in our three focus research areas of Psychiatry & Neurology, Oncology, and Regenerative Medicine/Cell Therapy, as well as working on Frontier business where we expect synergies with development of pharmaceuticals and the pharmaceutical business, with the aspiration to establish a position as a "Global Specialized Player" in 2033.

Moreover, in order to adapt to the "Time for Change" ahead of the post-LATUDA situation (after the loss of the exclusive marketing period for atypical antipsychotic LATUDA® in the U.S.), we indicated that Sumitomo Dainippon Pharma will work to rebuild the business foundation through the "establishment of growth engine" and the "building of flexible and efficient organization."

### Positioning of the revision of Mid-term Business Plan 2022

Under the Mid-term Business Plan 2022, Sumitomo Dainippon Pharma has been working to rebuild the business foundation. However, there have been significant changes in the medium- to long-term business outlook, including events such as the discontinued development of napabucasin for pancreatic cancer, which had been expected to be a revenue driver post-LATUDA. As a result of these changes, we decided to form the strategic alliance with Roivant Sciences Ltd. Through this strategic alliance, our group has acquired vibegron and an interest in Myovant which owns relugolix, which are expected to become major products as a revenue base for the time being, and we have also been working to develop the best in class\* pharmaceuticals with a focus on the value of these compounds.

We also discontinued development of SB623 and dasotraline and revised sales plans downwards for new products launched in North America, including Lonhala<sup>®</sup> Magnair<sup>®</sup> for chronic obstructive pulmonary disease (COPD) and KYNMOBI<sup>®</sup> for treatment of Parkinson's Disease OFF episodes. In addition, the environment has changed significantly with acceleration of measures to curb drug costs in Japan, China, and the U.S. among other factors.

In light of these circumstances, Sumitomo Dainippon Pharma revised the financial goals of Mid-term Business Plan 2022 in May 2021.

\* Best in class: There are existing drugs, but new drugs that have a clear advantage over the existing drugs.



### Vision and aim for 2033 (Updated October 2019)

### Revision of financial goals and future outlook

Although the discontinuation of development for napabucasin and declining revenue due to such factors as measures to curb drug costs in Japan and China will be offset by sales of new products relugolix and vibegron, core operating profit is expected to fall, partly due to the impact of sales-related expenses for the two products.

To achieve medium- to long-term growth, Sumitomo Dainippon Pharma will strive to maximize profit and reduce risk by partnering on a global scale. We will continue to invest more than ¥90 billion a year in research and development, and optimize the allocation of investment with the greatest focus on the development of compounds expected to become major products in the Psychiatry & Neurology area, the Oncology area, and the Regenerative Medicine/Cell Therapy field. We will also continue to promote management efficiency on a global basis by strengthening our foundation and structure, including the pursuit of cost synergies through enhanced collaboration between our group companies in North America.

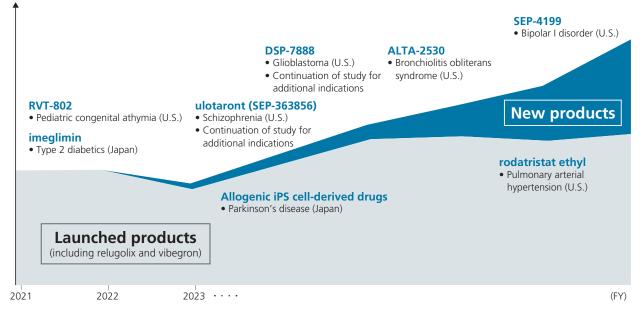
In fiscal 2023, we expect revenue to decline due to the loss of the exclusive marketing period for LATUDA® in the U.S. However, we will minimize the impact of declining revenue with mainstay products, including vibegron and Myovant's relugolix, and aim for rapid recovery and sustained growth in business performance from fiscal 2024 onward thanks to in-house development compounds such as ulotaront (SEP-363856).

### **Review of financial goals**

	FY2022 Financial Goals (Published in April 2019)	FY2022 Financial Goals (Revised in May 2021)	Outlook for FY2025	
Revenue	¥600 billion	¥600 billion	Approximately ¥750 billion	
Core operating profit	¥120 billion	¥60 billion	Approximately ¥120 billion	
ROIC	10%	3%	Long-term vision	
ROE	12%	3%	ROE of 10% or more in	
5-year average payout ratio	20% or higher	20% or higher	latter half of the 2020s	

Exchange rate: 110 yen to the dollar

### **Revenue** (Diagram)



**Mid-term Business Plan 2022** 

# Mid-term Business Plan 2022: Reshaping the Business Foundation

Under the Mid-term Business Plan 2022, we will significantly reshape our business foundation through the "establishment of growth engines" and the "building of a flexible and efficient organization."

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

Another strategy pillar of the Mid-term Business Plan 2022 is the "building of a flexible and efficient organization" to support these growth engines. We will use digital transformation to enable our organization and talent to identify changes in the external environment and adapt proactively and flexibly, while maintaining the ability to do things diligently, which is called "CHANTO": deliver the highest performance.



### Basic Policy II Building of flexible and efficient organization "CHANTO"

Flexible and efficient organization and operations	⇒ P.48
Corporate culture and talent to drive innovation	⇒ P.49
Digital transformation	⇒ P.54

Basic Policy I Strategy 1: Enhance innovation base with new approaches to drug discovery Strategy 2: Deliver the highest performance of clinical development Strategy 3: Pipeline expansion through strategic investment

Strategy 4: Regional strategy centering in Japan, North America and China

## Basic Policy I Establishment of growth engine

## Strategy 5: Launch frontier business

Basic Policy II

Material issues Sumitomo Dainippon Pharma has set targets and KPIs, and we have provided a list of them on pages 25–26.

#### Enhance innovation base with new approaches to drug discovery Strategy 1 Explore innovation leveraging by digital technologies and big data Prioritize the three focus areas + 3 1 Infectious diseases and Vaccines Regenerative / Cell Psychiatry & Oncology Infection Neurology Engage in initiatives to realize Precision Accelerate external collaboration Medicines 2 4 Psychiatry & Neurology Psychiatry & Regenerativ / Cell Regenerative / Cell Oncology Infection Oncology Infection Neurology

In addition to R&D 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 and the development of best in class pharmaceutical products focused on value.

### Accelerate external collaboration

Taking advantage of our unique strengths, we are working to shift to and promote drug discovery utilizing our networks with outside partners, centering on our presence in Japan and the United States.

### Leveraging digital technologies and big data

To help increase the probability of success of R&D, we are

taking on the challenge of innovation utilizing a wide range of digital technologies and big data, such as genome information, imaging, and clinical data. We are also promoting the use of our proprietary digital technologies, such as DrugOME, which we have acquired through our strategic alliance with Roivant.

## Engage in initiatives to realize Precision Medicines

We are working to make precision medicine a reality through a deeper understanding of pathology and etiology based on cutting-edge science and technology, as exemplified by the utilization of biomarkers.

Material issues Development of innovative products and healthcare solutions / Contributing to the development of science		
Targets	<ul> <li>Continuous development of pharmaceuticals in areas with high unmet medical needs</li> <li>Development of healthcare solutions to respond to the future healthcare needs centered on areas where synergies with the pharmaceutical business can be expected</li> </ul>	
KPIs	• Progress on early-stage development pipeline: In the Psychiatry & Neurology and Oncology areas, we use the number of compounds advancing into clinical studies as an indicator to help enhance the early development stage.	
	• Progress on development of modalities: To emphasize drug discovery of new modality beyond small molecules (cells / tissues / organs, gene therapy, protein formulations, etc.), we evaluate efforts to develop modality.	
	• Work motivation of research & development staff: Looking at company-wide engagement surveys, we measure the motivation of our R&D personnel based on evaluation scores, such as a sense of responsibility and satisfaction for work, a sense of contribution to customers and society, acquisition of professional skills, and demonstration of individuality and ability.	

### Mid-term Business Plan 2022

### Basic Policy I Establishment of growth engine

### **Psychiatry & Neurology area**

Based on our proprietary drug discovery platform, built by incorporating cutting-edge technologies including AI and patient-derived iPS cells, we will work to develop therapeutic agents for psychiatric disorders in areas of high unmet need, neurodegenerative disease modifying therapies, as well as the treatment of peripheral symptoms of neurodegenerative diseases (ex. psychiatric symptoms, etc.).

### The direction of drug discovery

### Psychiatric disorders (schizophrenia, depression, developmental disorders, and psychiatric symptoms related to neurological disorders)

We will focus on research and development for the treatment of schizophrenia, depression, developmental disorders, and psychiatric symptoms in neurological disorders considering of these conditions as "modulation of genes and neural circuits." In particular, we will base our drug discovery work on neural circuit pathology, aiming to create new therapeutic agents to address unmet medical needs.

## Neurological disorders (dementia, Parkinson's disease, rare diseases)

We will focus on drugs for dementia, Parkinson's disease, and rare diseases as we enter an era of transformative change toward drug discovery methods approaching the root cause of these conditions. In this area, our goal is to develop life changing treatments for neurodegenerative

#### Initiatives to Utilize Our Competitive Technology/Know-how

- Extensive experience with clinical studies
- Exploratory/development research using cutting-edge technology
- Organizational structure to support product creation on a consecutive basis

Enhance probability of success in clinical studies Sumitomo Dainippon Pharma 15% (6-8% industry average) Further improvement by utilization of biomarkers

### Expand early pipeline

**12 candidates in the past 3 years** 4 of them are in clinical development diseases through drug discovery based on molecular pathological mechanisms.

## Exploratory/development research using cutting-edge technology

We are working to identify new targets for drug discovery through translational research using EEG and brain imaging data obtained during the development of LATUDA® and ulotaront (SEP-363856), as well as our proprietary data-driven in silico drug discovery method. We are also attempting to improve our probability of success in R&D by selecting biomarkers to be used in both clinical and pre-clinical studies. In addition, we are verifying the effectiveness of compounds in disease model animals using optogenetics technology.

Furthermore, we are tackling new challenges such as the utilization of real-world data using DrugOME, acquired from Roivant, the utilization of evaluation systems that reflect human pathologies prepared using patient-derived iPS cells, and the development of new modalities beyond small molecules.

As a result of these initiatives, we developed seven candidate drugs in FY2020.

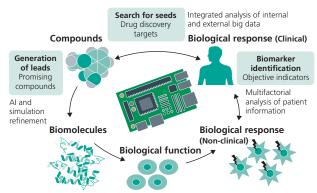
## Organizational structure to support product creation on a consecutive basis

In addition, we are promoting an organizational structure that supports product creation, such as the Research Project System adopted to allow researchers who have come up with project themes serve as Project Leaders up to the clinical stage, as well as cross-sectional virtual

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

### In silico drug discovery

In silico = technology applied to drug design fully utilizing computational science on computers.



 Basic Policy I
 Strategy 1: Enhance innovation base with new approaches to drug discovery

 Strategy 2: Deliver the highest performance of clinical development

 Strategy 3: Pipeline expansion through strategic investment

 Strategy 4: Regional strategy centering in Japan, North America and China

 Strategy 5: Launch frontier business

Basic Policy II

one-team activities to solicit ideas beyond the boundaries of our organizations. To date, DSP-1181 and DSP-0038 created under the Research Project System have advanced into clinical studies.

We are also actively promoting the creation of innovative pharmaceutical products through open innovation by utilizing the technologies and seeds of academia and biotech companies to bring novel ideas into drug discovery.

### **Oncology** area

Working on drug discovery activities in pursuit of our competitive edge while focusing on assessing the value of the current pipeline and improving the probability of success

### **Future policy**

We are devising ways to improve the probability of successful development and strike an appropriate balance between investment and return by, for example, acquiring data that allow us to make decisions on development stage transition from early on, as well as bolstering efforts to identify optimum cancer types/patients in short-term, small-scale studies.

In addition to utilizing the technologies, seeds, and know-how acquired and accumulated through partnerships with academia and biotech companies as well as our own in-house research, we will build our proprietary pipeline by utilizing unique digital technologies, such as DrugOME acquired through a partnership with Roivant, and strengthening efforts to develop new modalities.

### Basic strategies for drug discovery research

We have formulated four basic strategic pillars to meet unmet medical needs and develop competitive candidate compounds for development on an ongoing basis.

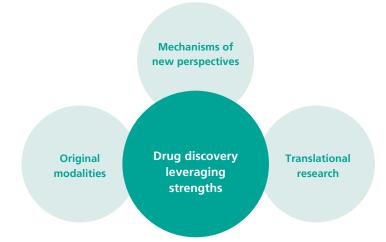
First, we will focus on drug discovery targets that enable us to obtain early clinical POC with clearly targeted patients while also seeking to select drug discovery targets by using clinical information big data analysis and patient-derived samples. The second is the acquisition of technologies such as new drug discovery modalities. We are pursuing our competitive edge by proactively implementing drug discovery and expanding its range. Thirdly, we will strengthen collaboration with the clinical development departments to advance translational research and focus on biomarker research, including the development of PD (pharmacodynamics) markers that will enable us to obtain early POC and the acquisition of markers that will enable patient selection. The last is to maintain and strengthen our relationships with KOLs. We will use the information obtained to formulate initial clinical development strategies.

### Strengthening the global R&D structure

We aim to develop innovative products on an ongoing basis under the global R&D structure consisting of the DSP Cancer Institute and the Oncology Clinical Development Unit in Japan, as well as Sumitomo Dainippon Pharma Oncology, Inc. in the United States.

We will proceed with research and development at an appropriate scale, including joint research to explore indications by cancer type.

### Initiatives to develop a pipeline with a competitive edge



### **Mid-term Business Plan 2022**

### **Basic Policy I Establishment of growth engine**

### Regenerative medicine / cell therapy field

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

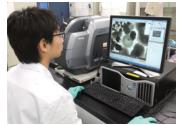
### We will aim for sales revenue in the Regenerative Medicine/Cell Therapy business of about ¥200 billion on a global scale by around 2030

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. Thus, we are implementing six research and development projects aimed at providing therapies to patients with unmet medical needs, as well as therapies designed for radical cure.

We are steadily promoting research projects mainly in Neurology and Ophthalmology areas in pursuit of 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) and aim for global expansion (Japan, the United States, and Asia). First, we intend to realize financial contributions mainly in Japan and the United States during the next MTBP period (fiscal 2023–2027).

Comprising two aboveground levels with a total floor area of 2,915 m<sup>2</sup>, Sumitomo Dainippon Manufacturing Plant for Regenerative Medicine & Cell Therapy (SMaRT) 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.



Research in progress at the Regenerative & Cellular Medicine Kobe Center

### From single cells to tissues and organs-taking on the challenge of new therapies through modality development

Through regenerative medicine and cell therapy products,

we look to provide novel fundamental therapies for diseases for which only symptomatic relief and temporary suppression of progression have been available to date. To this end, we are conducting research and development to create complex structures such as tissues and organs from iPS cells and put them into practical use as regenerative medicine and cell therapy products.

In addition to our world-leading expertise in regenerative medicine and cell therapy field, we have the production infrastructure, know-how, and human resources to commercialize our products and therapies. We are also working for pharmaceutical deregulation aiming at commercialization.

### 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).

### **Main Projects**

### Drug discovery to treat antimicrobial resistance (AMR) bacterial infections

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

### **Development of adjuvanted vaccines**

We are implementing development of adjuvanted vaccines by combining TLR7 agonist adjuvant, our foundation technology, with promising antigens from outside research institutes. We are working on malaria vaccines with Ehime University, etc. and a universal influenza vaccine 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.

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Material issues Sumitomo Dainippon Pharma has set targets and KPIs, and we have provided a list of them on pages 25–26.



With an eye on a post-LATUDA era, we are implementing a variety of measures to reinforce our ability to deliver the highest performance even in areas of high uncertainty (CHANTO).

#### Goal setting for securing success

In addition to designing clinical studies for ulotaront in patients with schizophrenia, with its future clinical and medical economic significance taken into consideration, we have set goals to maximize the compound's value, if approved, including the identification of second and third indications. We strive to make objective, evidence-based evaluations and decisions by setting optimal clinical study designs based on our experience, knowledge, and know-how in the areas of psychiatry & neurology, utilizing adaptive design, which is a leading clinical study design in the oncology area, and conducting translational research in both areas. In addition, as an approach to diseases with high unmet medical needs, we are working on regenerative medicine and cell therapy field and Frontier Business projects that will address future healthcare needs.

#### Management of business risks

We plan to promote partnering on a global scale to share risks and complement resources. In the oncology area, while strengthening our efforts to identify optimal indications in small-scale studies, we are also actively promoting partnership and out-licensing activities.

# Adopting cutting-edge technology and utilizing the regulatory system

To improve the probability of success of clinical studies, we use biomarkers to select appropriate patient populations. For example, in clinical studies for DSP-7888 targeting glioblastoma, biomarkers are used to screen for



### Basic Policy I Establishment of growth engine

a specific patient population. By utilizing medical information databases (receipt information, genome information, regional cohorts, disease registries, etc.) as well as AI, we are also promoting clinical development by appropriately designing clinical studies, including eligibility criteria, endpoints, and study scale. In addition, we look to obtain early approval and reduce development costs by utilizing a wide range of programs available, such as the SAKIGAKE designation system, orphan drug designation, and accelerated approval program.

Development pipeline (as of July 29, 2021, not including drugs with additional indications and usages)

Development products	ppment products Proposed indication Development stage		ts Proposed indication Development stage		Region	Launch target
ulotaront (SEP-363856)	Schizophrenia	Phase 3 Phase 2/3	U.S. Japan China	FY2023 (U.S.) Latter half of the 2020s (Japan/Asia)		
SEP-4199	Bipolar I depression	Phase 2	U.S. Japan	Latter half of the 2020s (U.S./Japan)		

#### Psychiatry & Neurology area ..... New compounds under development: 10

#### Oncology area ..... New compounds under development: 9

Development products	ent products Proposed indication		Region	Launch target
DSP-7888	Glioblastoma	Phase 3	U.S. Japan	FY2024
dubermatinib (TP-0903)	Acute myeloid leukemia (AML)	Phase 2	U.S.	TBD

#### Regenerative medicine / cell therapy field ..... Number of projects: 6

Projects	Proposed indication	Development stage	Region	Launch target
RVT-802	Pediatric congenital athymia	BLA resubmitted in April 2021	U.S.	FY2021
Allo iPS cell-derived dopamine neural progenitor	Parkinson's disease	Investigator-initiated clinical study	Japan	FY2023*1
Allo iPS cell-derived retinal pigment epithelium	Age-related macular degeneration (AMD)	Preparing to start clinical study	Japan	FY2025*1

\*1 Launch target is based on our goal pending agreement with partners

#### Other area ..... New compounds under development: 4

Development products	Proposed indication	Development stage	Region	Launch target
lefamulin	Bacterial community- acquired pneumonia	Phase 3	China	FY2023
rodatristat ethyl	tristat ethyl Pulmonary arterial hypertension (PAH)		U.S.	Latter half of the 2020s

#### Frontier business ..... Number of projects: 5\*2

Projects	Development stage	Region	Launch target
Mobile app for management of type 2 diabetic patients	Phase 3	Japan	FY2022

\*2 Already published (as of July 29, 2021)

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#### Features of major products under development

#### ulotaront (SEP-363856)

Ulotaront is a TAAR1 (trace amine-associated receptor 1) agonist with serotonin 1A (5-HT1A) agonist activity, has a distinct mechanism of action from currently available treatments for schizophrenia. Phase 2 study results, published in the *New England Journal of Medicine*, supported efficacy in positive and negative symptoms of schizophrenia while demonstrating a safety profile with notable similarities to placebo for extrapyramidal symptoms, weight gain, increases in lipid and glucose, and prolactin elevation. Ulotaront received U.S. FDA Breakthrough Therapy designation for the treatment of schizophrenia. If approved, we expect it to grow into a blockbuster at its peak, including additional indications.

#### SEP-4199

SEP-4199 is a non-racemic ratio of amisulpride enantiomers. It is designed to increase the ratio of R-amisulpride to S-amisulpride in an 85:15 ratio aiming to increase levels of serotonin 5-HT7 activity intended to enhance antidepressant efficacy and to produce reduced levels of dopamine D2 receptor occupancy appropriate for the treatment of bipolar depression. It could also be a new treatment option for bipolar depression, for which there have been few therapeutic agents.

#### **DSP-7888**

DSP-7888 is the world's first immunotherapeutic cancer peptide vaccine derived from WT1 protein, designed to induce both helper T cells and WT1-specific cytotoxic T lymphocytes (CTLs). By adding a helper T cell-inducing peptide, improved efficacy over that observed with a CTL-inducing peptide alone may be achieved. DSP-7888 is potentially an option for a wide range of patients.

#### dubermatinib (TP-0903)

Dubermatinib (TP-0903) is an inhibitor of multikinase, including AXL receptor tyrosine kinase inhibitor, under development in a research group-initiated clinical study. Based on its pre-clinical study data, TP-0903 is potentially effective in AML with a TP53 mutation or complex chromosomal karyotype.

#### **RVT-802**

RVT-802 is the world's first one-time regenerative therapy of cultured human thymus tissue for the treatment of fatal/congenital diseases. It is designated as Regenerative Medicine Advanced Therapy in the United States.

#### Allogenic iPS cell-derived drugs

In cooperation with the partners in the industry-academia collaboration, we are promoting the commercialization of regenerative medicine/cell therapy using iPS cells, mainly allogenic (healthy patients), for Parkinson's disease, age-related macular degeneration (AMD), retinitis pigmentosa, spinal cord injury, and renal failure.

**Parkinson's disease:** A SAKIGAKE-designated medicine in Japan is under joint development with the Center for iPS Cell Research and Application (CiRA) at Kyoto University. We are preparing to start clinical studies in the United States in FY2022.

**Age-related macular degeneration:** Through joint development with Healios K.K., we are preparing to start clinical studies in Japan in FY2021.

#### lefamulin

Lefamulin is a pleuromutilin antimicrobial agent and a novel anti-infective therapeutic drug with a mechanism of action different from existing antimicrobial agents. In the United States, it is marketed as XENLETA® by Nabriva.

#### rodatristat ethy

Rodatristat ethy is a tryptophan hydroxylase inhibitor designed to inhibit peripheral production of serotonin without transfer to the brain. A disease modification effect is potential in pulmonary arterial hypertension rather than symptomatic therapy.

#### **Frontier business**

In addition to a mobile application for type 2 diabetes management, we are working with our partners to promote projects as follows: digital devices related to dementia and nursing care, virtual reality content aimed at alleviating social anxiety disorder, assistive devices for improving motor dysfunction, and automated blood collection and stabilization devices targeting lifestyle-related diseases. We aim to launch multiple products from FY2022 to FY2025.

#### **Infectious diseases**

In collaboration with our partners, we are proceeding with projects (pre-clinical studies) for therapeutic drugs for antimicrobial resistance (AMR) bacterial infections, universal influenza vaccine, and malaria vaccines. We aim to commercialize them from the next MTBP period (fiscal 2023–2027) onward.

### Basic Policy I Establishment of growth engine

#### Message from the CSO



#### **Toru Kimura**

Representative Director, Executive Vice President Chief Scientific Officer (CSO) Regenerative & Cellular Medicine Office, Regenerative & Cellular Medicine Kobe Center, Regenerative & Cellular Medicine Manufacturing Plant

# Deliver the highest clinical development performance for consistent product creation

We are currently promoting the Mid-term Business Plan 2022 aiming at establishing our position as a Global Specialized Player by 2033. What we need to do is to optimize resource allocation in order to launch products in the way planned from a long-term perspective while steadily moving forward with development of in-house compounds as well as in-licensed compounds.

In this respect, the strategic alliance with Roivant has had great impact. From the pipeline we acquired or acquired an interest in, the development of relugolix and vibegron, potential near-term blockbusters, progressed smoothly, enabling us and Myovant to start marketing them in the United States. These products are expected to make contributions to revenue in the future minimizing the impact of a significant decline in revenue from LATUDA<sup>®</sup>, whose exclusive marketing period in the U.S. will expire in February 2023.

The current challenge in our R&D strategy is to continue to deliver products in order to enrich the pipeline that will become the next growth driver following vibegron and Myovant's success with relugolix.

In the Psychiatry & Neurology area, we are steadily developing assets that are expected to contribute to future revenue, such as ulotaront (SEP-363856) and SEP-4199, which were created in-house. We also aim to continue creating products through exploratory research using cutting-edge technologies. In the Oncology area, although we decided to discontinue the development of napabucasin in March 2021, since making a full-scale entry into this area in 2011, the Group has steadily accumulated R&D knowledge and know-how in the oncology area and is pushing forward with the development of nine compounds, including DSP-7888, created in-house. In the Regenerative Medicine & Cell Therapy field, we aim to provide treatment options to patients with diseases that have no sufficient treatment, as well as radical cures, by utilizing our world-leading technologies, knowledge, and human resources.

Aware that the fruits of R&D are an accumulation of efforts made over a long time, we believe it is important to launch products consistently until 2033, for now, through appropriate investment in high-priority R&D projects.

#### Increasing information transparency within the organization to optimize the R&D portfolio

When managing our organization as CSO, I focus on information transparency. At a pharmaceutical company, risks have to be taken when making decisions on R&D investment. When allocating resources, I believe it is particularly important to recognize the risks involved in advancing an asset under development to the next stage and to share them within the entire organization. I believe that convincing decision-making should lead to positive actions from each and every employee, as well as the revitalization of our organizations.

Our Group has an independent R&D structure for each area and field, and each of these organizations conducts R&D activities by taking advantage of agility and accelerated Basic Policy I Strategy 1: Enhance innovation base with new approaches to drug discovery Strategy 2: Deliver the highest performance of clinical development Strategy 3: Pipeline expansion through strategic investment Strategy 4: Regional strategy centering in Japan, North America and China Strategy 5: Launch frontier business

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decision-making on its own. While this is a strength, we have become aware of the problem that why and how an organization's decision has been made is not adequately shared with other organizations. Under these circumstances, starting from fiscal 2020, I decided to get directly involved in essential decision-making on R&D across all the R&D areas and introduced a system for sharing information, in an inter-organizational manner, about how to launch products that will support revenue in the medium-term and those in the long-term. We are building a balanced R&D portfolio by harmonizing our organizations while maintaining the independence and strengths of each of them.

#### Empowering the research organizations and developing human resources who will lead the future

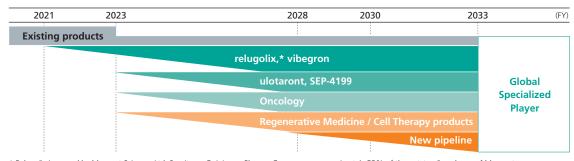
In 2017, we introduced a Research Project System with the purpose of

empowering the research organizations in Psychiatry & Neurology area. Under this system, the Project Leaders of research projects are selected irrespective of age or one's career in the company based on factors such as scientific knowledge on the research themes and enthusiasm and given authority on budget and personnel evaluation so that the Project Leader is consistently responsible for the research project from the early stage through the later stages.

About 25 years ago, when I was still in my early 30s, the former Sumitomo Pharmaceuticals established a Frontier Laboratory System that allowed young researchers to work on highly innovative research themes based on long-term perspective. By using this system, I myself learned how difficult it is to manage an organization, in addition to having my perspective broadened as a researcher. Based on my experience at that time, when designing the current Research Project System, I adopted a system that would allow Project Leaders to concentrate on promoting their research project without having to spend too much time on administrative work such as inter-organizational coordination. I believe this system offers a very good opportunity for our employees serving as leaders to gain valuable experience.

In addition to organizational empowerment through such initiatives, as a result of promoting research projects incorporating cutting-edge technologies, our productivity has increased by 2 to 3 times over previous levels, as exemplified by the seven candidate compounds for clinical development we identified in fiscal 2020. We will continue to develop human resources who will lead the future, while improving the R&D framework in areas other than Psychiatry & Neurology and strengthen our R&D infrastructure to keep generating innovation.

#### Research and Development Strategy to Become a Global Specialized Player



\* Relugolix is owned by Myovant Scineces Ltd. Sumitomo Dainippon Pharma Group owns approximately 53% of the outstanding shares of Myovant. **Sumitovant products will be main source of revenue for the next 10 years including R&D expense** 

- In the meantime, development and launch of products for post-LATUDA will be progressing
- Contributing to health care as a "Global Specialized Player" after 2033

### Basic Policy I Establishment of growth engine

#### Strategy 3 Pipeline expansion through strategic investment

We set a range of ¥300 billion to ¥600 billion for strategic investments in the Mid-term Business Plan 2022.

#### **Top Priority:**

Our top priority is developing a pipeline in Psychiatry & Neurology that will contribute to profits in fiscal 2023 and onward.

#### **Second Priority:**

Our second priority is developing a pipeline and technology in three focus areas that will contribute to profits in fiscal 2028 and onward.

#### Strategic alliance with Roivant Sciences Ltd.

Sumitomo Dainippon Pharma actively promotes strategic investment in M&A and in-licensing to expand its the development pipeline. As noted above, in our Mid-term Business Plan 2022 ("the MTBP"), we initially mapped out a strategy of obtaining pipeline assets in the Psychiatry & Neurology area that were expected to contribute to revenue in fiscal 2023 and beyond. We did not find compelling candidates to meet our goals, however, we decided to study a broader range of options in an effort to sustain business growth over the medium to long term.

In fiscal 2019, we acquired or acquired an interest in a pipeline numerous pipeline assets, some of which have the potential to be blockbusters, through a strategic alliance with Roivant Sciences Ltd. ("Roivant").

Our alliance partner, Roivant, has a unique business model. Roviant purchases discontinued compounds from other companies and seeks to resume their development, as appropriate. As part of this model, Roviant established subsidiaries known as Vants—small and agile companies capable of robust and efficient development efforts—each dedicated to a different therapeutic area and compound.

Under the strategic alliance, besides acquiring all of the shares of Sumitovant Biopharma Ltd. ("Sumitovant"), a new company to which five of Roivant's subsidiaries have been transferred, Sumitomo Dainippon Pharma acquired approximately 12% of the shares of Roivant. The total investment for this strategic alliance was approximately ¥330 billion, which is our biggest investment ever.

Because two of the products developed by the entities in which we acquired equity interests —relugolix\*1 and vibegron — had already been launched in other

countries, we assumed that these two products had a high likelihood of gaining regulatory approval. These products were launched in the U.S. in 2021. We hope that these products will help guide our post-LATUDA growth trajectory. We plan to advance research and development in our three focus research areas of Psychiatry & Neurology, Oncology, and Regenerative Medicine / Cell Therapy with the cash generated by these products, in a bid to establish new growth engines for the coming generations.

\*1 Relugolix and MVT-602 are owned by Myovant Scineces Ltd. Sumitomo Dainippon Pharma Group owns approximately 53% of the outstanding shares of Myovant.

#### Future investment policy

We will work to achieve early market penetration and maximize the value of relugolix and vibegron, which we obtained through the strategic alliance. With this initiative, we are hoping to minimize the impact of LATUDA®'s sales decline in fiscal 2023 and thereafter to realize sustained growth of our business.

As of today, we do not anticipate any large investment projects other than our strategic alliance with Roivant during the period of the MTBP, but we will continue to seek investment opportunities to obtain development pipelines for products that could be marketed using our existing infrastructures, potentially contributing to our earnings early. 

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Signing of a strategic alliance agreement with Roivant Sciences (procedure completed in December 2019)

#### Purpose

- To acquire growth engines after LATUDA® LOE in the U.S.
- To accelerate digital transformation

#### **Stock Acquisition**

#### Sumitovant Biopharma

- Myovant Sciences\*<sup>2</sup>
- Urovant Sciences
- Enzyvant Therapeutics
- Altavant Sciences
- Spirovant Sciences

Consideration

Approx. US\$3 billion (approx. 330 billion yen)

#### Healthcare Technology Platforms Transfer

#### DrugOME

Platform to accelerate pipeline acquisition /clinical development by using unique data analyses

#### **Digital Innovation**

Platform to improve operational efficiency by utilizing healthcare-IT-related technology

+ Acquired certain key employees involved in its healthcare technology platforms and 12% of Roivant shares

\*2 Sumitomo Dainippon Pharma Group owns approximately 53% of the outstanding shares of Myovant.

#### Launched products acquired through the strategic alliance with Roivant (as of July 29, 2021)

Compound	Modality	Brand name	Indication	Therapeutic area	Country launched	Time launched
relugolix	Small molecular	ORGOVYX®	Advanced prostate cancer	Oncology	U.S.	January 2021
(Myovant)	Small molecular (combination tablet)	MYFEMBREE®	Uterine fibroids	Women's health	U.S.	June 2021
<b>vibegron</b> (Urovant)	Small molecular	GEMTESA®	Overactive bladder (OAB)	Urology	U.S.	April 2021

#### Development pipelie acquired through the strategic alliance with Roivant (as of July 29, 2021)

Compound	Modality	Indication	Therapeutic area	Development phase	Milestone
	Small molecular	Advanced prostate cancer	Oncology	MAA submitted (Europe)	MAA approval (Europe)
relugolix		Uterine fibroids	Women's health	MAA approved (Europe)	Launches in EU countries (by Gedeon Richter Plc.)
(Myovant)	Small molecular (combination table)	Endometriosis	Women's health	NDA submitted to FDA (U.S.) Preparing for MAA submission (Europe)	NDA approval (U.S.) MAA submission (Europe, latter half of 2021)
MVT-602 (Mvovant)	Oligopeptide	Female infertility	Women's health	Phase 2	Results of Phase 2 study
<b>vibegron</b> (Urovant)	Small molecular	OAB in men with benign prostatic hyperplasia (BPH)	Urology	Phase 3	Topline results (latter half of 2022)
URO-902 (Urovant)	Gene therapy	OAB	Urology	Phase 2	Results of Phase 2 study
RVT-802 (Enzyvant)	Regenerative Therapy	Pediatric congenital athymism	Rare disease	NDA re-submitted to FDA (U.S.)	FDA PDUFA (U.S., October 2021)
rodatristat ethyl (Altavant)	Small molecular	Pulmonary arterial hypertension (PAH)	Respiratory	Phase 2	Results of Phase 2 study
ALTA-2530	Recombinant	Bronchiolitis obliterans syndrome (BOS)	Respiratory	Preclinical	IND submission (2023)
(Altavant) protein	Chemical lung injury	Respiratory	Preclinical	IND submission (2022)	
SP-101 (Spirovant)	Gene therapy (AAV)	Cystic fibrosis	Respiratory	Preclinical	IND submission (2022)
SP-102 (Spirovant)	Gene therapy (LVV)	Cystic fibrosis	Respiratory	Preclinical	IND submission (2025)

### Basic Policy I Establishment of growth engine

Regional strategy centering in Japan, North America and China Strategy 4 Japan Initiatives to optimize the structure to maintain sustainable revenue for business operations in Japan Europe Collaboration with partners China & Asia Maximize sales/profits through partnerships with external parties and promotion of internal cost reduction Business expansion to geographical areas likely to contribute to our profits Oceania Collaboration with partners Main Points of Regional Strategy (FY2018-2022) **North American Market Japanese Market** Transform to steady growth Maximize product value in the Psychiatry & • Maximize product value in the Diabetes area (Trulicity<sub>®</sub>, Neurology area Equa®/ EquMet®, and TWYMEEG®) • Maximize value of LATUDA® and product value of • Maximize product value in the Psychiatry & Neurology area KYNMOBI® while maintaining growth of APTIOM® (TRERIEF®, LATUDA®, and LONASEN® Tape) • Accelerate development of ulotaront (SEP-363856) and other pipeline assets including SEP-4199 Initiatives to optimize the structure to maintain sustainable revenue for business operations in Japan Expedite efforts to establish new products owned by • Business operation based on the assumption of shrinkage Sumitovant and Myovant as growth drivers of the size of pharmaceutical market in Japan • Achieve smooth market penetration and maximize product • Review global head office functions for optimization value of ORGOVYX® MYFEMBREE® and GEMTESA® • Maximize sales/profits through partnerships with external Pursue opportunities for strategic investment & parties and promotion of internal cost reduction partnership Expand pipeline • Explore co-promotion partnerships, leveraging our commercial footprint

#### Optimize business operation

- Continued initiatives for optimization of infrastructure in North America
- Initiatives for creation of cost synergy by strengthening alliance among subsidiaries

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Promote development of promising new compounds while maximizing marketed therapies to contribute to post-LATUDA growth trajectory

> Latin America Collaboration with partners

#### **Chinese & Asian Market**

#### Implement business strategy for Asian market

- Drive business strategy and expand pipelines in the Asian market
- Maximize sales/profits through partnerships with external parties and promotion of internal cost reduction
- Business expansion to geographical areas likely to contribute to our profits
- Pursue business opportunities in the Regenerative Medicine / Cell Therapy field and Frontier business

#### **Further expand China business**

- Reinforce business infrastructure as the third pillar after Japan and North America
- Maximize revenue from MEROPEN®
- Achieve smooth market penetration and maximize product value of new products in the Psychiatry & Neurology area (LONASEN® and LATUDA®)
- Participate in global development projects

#### Reinforce business in East and Southeast Asia

- Reinforce business functions in subsidiaries in Singapore, Thailand, and Taiwan
- Maximize revenue from MEROPEN<sup>®</sup> and LATUDA<sup>®</sup> through strengthened alliances with local partners

#### Japanese market

# Achievements from FY2018 through July 31, 2021

#### FY2018

• TRERIEF® (Parkinsonism in dementia with Lewy bodies): Indication added

#### FY2019

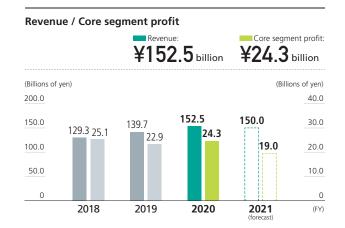
- Equa® and EquMet® (Type 2 diabetes): Marketing alliance
- LONASEN<sup>®</sup> Tape (Schizophrenia): Launched
- RETHIO<sup>®</sup> (Conditioning treatment prior to autologous hematopoietic stem cell transplantation (HSCT)): Launched
   FY2020
  - LATUDA<sup>®</sup> (Schizophrenia, bipolar depression): Launched
  - Activities of online MR<sup>™</sup> and vMR<sup>®</sup> started
  - LONASEN® tablet/powder (Schizophrenia in children): Dosage and administration added
  - S-RACMO Co., Ltd. established (CDMO business in the Regenerative Medicine / Cell Therapy field)

#### FY2021

• TWYMEEG<sup>®</sup> (Type 2 diabetes): Approved

#### Business activities in the Japan segment

In response to a market environment that is becoming increasingly challenging due to policies to curb drug costs, including the commencement of the off-cycle NHI drug price revision, we will further increase the efficiency of our business operations. We will maximize our product value in the Psychiatry & Neurology and Diabetes areas to become a genuinely dominant player in both of these focus areas. In the former area, we will expedite market penetration of LATUDA<sup>®</sup>, which was launched in June 2020, and in the latter, we will expand sales of Equa<sup>®</sup> and EquMet<sup>®</sup>, as well as Trulicity<sub>®</sub>, while at the same time preparing for the launch of TWYMEEG<sup>®</sup> (approved in June 2021) scheduled for September 2021.



### Basic Policy I Establishment of growth engine

#### North American market

#### Achievements from FY2018 through July 31, 2021

FY2018

LONHALA® MAGNAIR® (COPD): Launched

FY2020

- Sumitomo Dainippon Pharma Oncology, Inc. established (as a result of integration between Boston Biomedical, Inc. and Tolero Pharmaceuticals, Inc.)
- KYNMOBI® (OFF episodes in patients with Parkinson's disease): Launched
- Myovant Sciences Ltd. ("Myovant") entered into a development and marketing alliance involving relugolix with Pfizer Inc.
- ORGOVYX® (Advanced prostate cancer): Launched

  FY2021
  - GEMTESA® (Overactive bladder): Launched
  - MYFEMBREE® (Uterine fibroids): Launched

#### **Business activities in the North America segment**

In order to establish a post-LATUDA growth trajectory, we are pursuing business development opportunities with Sunovion Pharmaceuticals Inc. ("Sunovion") and the Sumitovant Group as a vehicle. Sunovion is currently focused on marketing KYNMOBI®, which was launched in September 2020, as well as further expanding growth of LATUDA®, one of the pillars of the Group's earnings, and further expanding earnings for APTIOM®. In addition, the Sumitovant Group, is focusing on assisting Myovant in achieving smooth market penetration and sales expansion of ORGOVYX® and MYFEMBREE®, which Myovant launched in January 2021 and June 2021, respectively, through co-promotion with Pfizer. Meanwhile, Urovant Sciences Ltd. ("Urovant") is working to increase the market penetration of GEMTESA®, which was launched in April 2021. In so doing, we will help increase the efficiency of marketing by Myovant and Urovant by taking advantage of Sunovion's strong sales infrastructure.

#### Revenue / Core segment profit Revenue Core seament profit: **¥281.5** billion ¥116.9 billion (Billions of yen) (Billions of yen) 349.7 350.0 200.0 281.5 280.0 160.0 262.3 252.5 117.5 116 9 119.3 210.0 114.5 120.0 140.0 80.0 70.0 40.0 0 0 2018 2019 2020 2021 (FY)

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#### **Chinese & Asian market**

#### Achievements from FY2018 through July 31, 2021

#### FY2018

- Business functions of a subsidiary in Singapore reinforced and its name changed to Sumitomo Pharmaceuticals Asia Pacific Pte. Ltd. (SPAP)
- Sumitomo Pharmaceuticals (Thailand) Co., Ltd. established (SPAP's subsidiary in Thailand)

#### FY2019

• LATUDA<sup>®</sup> (Schizophrenia): Launched (China)

FY2020

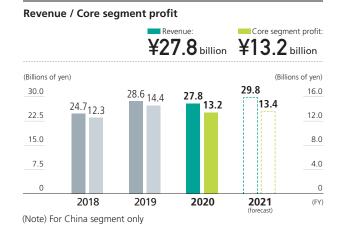
• Sumitomo Pharmaceuticals Taiwan Co., Ltd. established (SPAP's subsidiary in Taiwan)

FY2021

• Lefamulin and other development compounds in-licensed

#### **Business activities in the China & Asia segment**

The Group is reinforcing our business foundations in China, the third pillar of our business, while at the same time securing growth potential by consolidating our foothold in the Asian market. In the China segment, we will seek further growth by expanding sales of MEROPEN® (carbapenem antibiotic), LONASEN® (atypical antipsychotic), and LATUDA® (atypical antipsychotic), despite the ongoing measures to curb drug costs. In East and Southeast Asia, we will strive to expand sales of MEROPEN® and LATUDA® in collaboration with respective partner companies, while seeking to expand business in countries that best fit our pipelines.

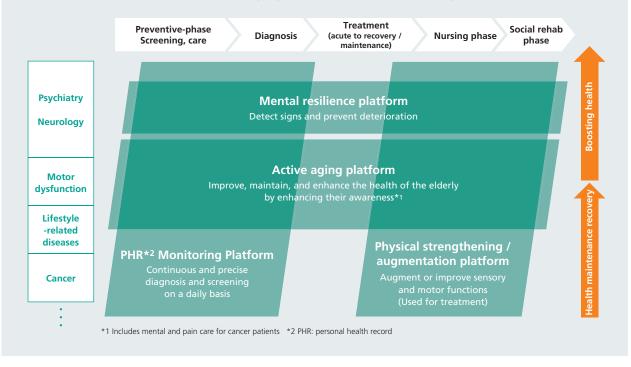




**Basic Policy II** 

#### Strategy 5 Launch frontier business

Anticipating the advent of an era in which it will be difficult to achieve the required level of well-being through pharmaceuticals alone, we are promoting frontier business with the aim of providing new healthcare solutions other than pharmaceuticals while also utilizing digital transformation (DX) technologies.



#### Vision of frontier business

# Contribute to "wide-ranging well-being" together with pharmaceutical products

Sumitomo Dainippon Pharma aims to contribute to the well-being of patients not only through treatment, but also through prevention, care, and social rehabilitation, all stages from before they recognize their illness until they return to life in society. As a "frontier business" that transcends the boundaries of conventional pharmaceutical companies, we are promoting the research, development, and commercialization of new non-pharmaceutical healthcare solutions in areas where synergies can be expected with the pharmaceutical business. These areas include "mental resilience" (the prevention of deterioration of neuropsychiatric disorders by detecting the signs at an early stage) and "active aging" (improving, maintaining, and enhancing the health of the elderly by enhancing their awareness).

#### Main projects (partners)

- Research/development of digital devices for dementia/nursing care (Sompo Japan Insurance and Aikomi)
- Development of virtual reality contents for social anxiety disorder (BehaVR)
- Research/development of healthcare devices and medical devices utilizing excellent biosignal processing technology and robot technology (MELTIN)
- Development of mobile application for management of type 2 diabetes (Save Medical)
- Development of automated blood collection/stabilization device for lifestyle-related diseases (Drawbridge Health)

# Basic Policy II Building of flexible and efficient organization

#### Overview

Sumitomo Dainippon Pharma is building a flexible and efficient organizational foundation instilled with CHANTO: delivery of the highest performance by simultaneously executing organizational and operational reform and nurturing corporate culture and talent to drive innovation in parallel with digital transformation to support the establishment of growth engines.

Under Flexible and efficient organization and operations we aim to pursue operational excellence and build an agile and flexible organization to proactively address changes in our business environment. Under Corporate culture and talent to drive innovation we aim to foster talent responsive to environmental changes and encourage innovation and flexibility. Under Digital transformation we aim to achieve both new value creation and operational reform through digital technology.

#### Basic policy II Building of flexible and efficient organization

#### "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

Flexible and efficient organization and operations	Corporate culture and talent to drive innovation	Digital transformation
<ul> <li>Pursue operational excellence</li> <li>Build agile and flexible organization</li> </ul>	<ul> <li>Proactively address changes in business environment</li> <li>Encourage challenge-oriented culture</li> </ul>	<ul> <li>Establish efficient operations</li> <li>Create innovative drugs and improve probability of success</li> <li>Use as healthcare solutions</li> <li>Part of growth engine</li> </ul>
⇒ P.48	⇒ P.49	⇒ P.54



#### Flexible and efficient organization and operations

Sumitomo Dainippon Pharma pursues operational excellence and builds agile and flexible organization to proactively address changes in business environment.

As one method of achieving this, we promote work style innovation to enhance our value proposition to society by enhancing employee satisfaction and capability through improvements to productivity and work-life balance.

#### Pursue operational excellence

- "Work style innovation" supported by digital technology
- Optimize resource allocation

#### Agile and flexible organization

- Ability to prepare for and respond to future changes
- Strategically deploy external resources

#### Work style innovation

#### Material issues

#### More sophisticated work styles Improvement of productivity

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.

Since fiscal 2019, we have held company-wide workstyle innovation lectures based on the idea that enhancing the skills of each employee is essential to shift to higher productivity work styles. We have also implemented time management training to give employees opportunities for improving their own work styles and to learn about methods and approaches for increasing productivity.

In fiscal 2020, due to the COVID-19 pandemic, we established and expanded communication infrastructure to enable all domestic employees (approx. 3,000) to work

remotely and promoted active utilization of web conferencing system. As a result, an increasing number of employees utilized teleworking, and since July 2020 we have maintained the percentage of employees working onsite at our Osaka and Tokyo head offices at 30% or less. Additionally, we have made efforts to maintain productivity by holding training to strengthen communication in teleworking and disseminated information and held events to maintain physical and mental health. In future, we will continue efforts to enhance work style innovation to create a virtuous cycle of improving productivity by achieving results while enjoying work through work-life balance, which can become blurred when teleworking.

#### Improvement of employee satisfaction

We value communication between management and employees, which includes lectures by directors at each business site and company-wide messages from the president and executive officers.

Starting in fiscal 2019, we undertook an employee

#### KPls

- Employee engagement
- Employee turnover rate

The aim of our work style innovations is improving productivity. In evaluating productivity, we emphasize employees' sense of fulfillment in their professional and private lives. We have decided to measure employee engagement and turnover rate in order to understand how fulfilling work tasks are and how much employees feel that they are contributing to society through their work.

### Basic Policy II Building of flexible and efficient organization

engagement survey—DSP Opinion ("MinOpi")—through the Motivation Cloud service, which surveys and measures levels of employee satisfaction and expectations. In fiscal 2020, we were awarded third place in the large company division of the Best Motivation Company Awards 2020. Going forward, we will continue to work to improve the satisfaction of employees in each department.

#### Virtuous cycle in work-life balance

Sumitomo Dainippon Pharma believes 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 in order to achieve our Corporate Mission.

We believe that it is important for employees to have full and satisfying roles in both their professional and private lives. We encourage employees to produce maximum results within specified work hours, then, after work and in their free time, engage in personal development, outside interests, and leisure time with their family. We feel that a mindset oriented toward boosting the quality of hours spent on work tasks will spur individual growth and, as a result, produce a virtuous cycle that leads to better results for the organization. Since fiscal 2017, we have been continuously promoting Work Style Innovation Meetings to take stock of tasks at each workplace and to review work styles and have been working to resolve issues.

#### Corporate culture and talent to drive innovation

While maintaining a "culture with resilient and detailed execution," we are fostering talent responsive to environmental changes and encourage innovation and flexibility.

We are promoting Project CHANTO to achieve goals toward the penetration and practice of CHANTO: delivery of the highest performance while responding to environmental changes, and are working to foster leaders and global talent.



# Reinforce desired culture and expected employee profile

- Corporate culture to be enhanced: challenge-oriented, transparency, positive attitude, proactivity to changes, perseverance
- Desired employee profile: professional who is proactive in adapting to changes and taking on a challenge, aspires to enhance value through personal development, and is positive and flexible

#### **Required measures for evolution**

- Management that encourages willingness to take on a challenge with proactivity to changes
- Increase investment in employee development
- Promote Diversity & Inclusion
- Penetration/practice of "CHANTO"

#### Basic Policy I

Basic Policy II Flexible and efficient organization and operations Corporate culture and talent to drive innovation Digital transformation

#### Penetration/practice of CHANTO

#### **CHANTO: delivery of the highest performance**

Our concept of CHANTO is the capability to continuously foster and deliver innovation to patients and other customers, while transforming our organization in flexible ways to adapt to changes in the world.

By simultaneously pursuing digital transformation, organizational and operational reform, and fostering a corporate culture and talent that drive innovation, we are building a flexible and efficient organizational foundation in which CHANTO is instilled.

#### **Promoting Project CHANTO**

Under the Mid-term Business Plan 2022, our vision is to establish ourselves in a position as a Global Specialized Player by 2033. To that end, we thought it was necessary for each one of our employees to be always aware of CHANTO and to make personal progress, and launched Project CHANTO in February 2020. In Project CHANTO, management formulated Conduct Guidelines (CHANTO) to achieve our corporate vision. By disseminating CHANTO throughout the Company, we aim to accomplish both the behavior modifications of each and every employee and the generation of individual and organizational results.

Executive Officers defined and articulated CHANTO in a workshop and formulated a set of five Conduct Guidelines to help employees when they are unsure of or worried about something. In disseminating and deploying the established Conduct Guidelines, CHANTO, we aim gain greater understanding of CHANTO by all employees in a fun manner through workplace-led initiatives.

#### **Five Conduct Guidelines**

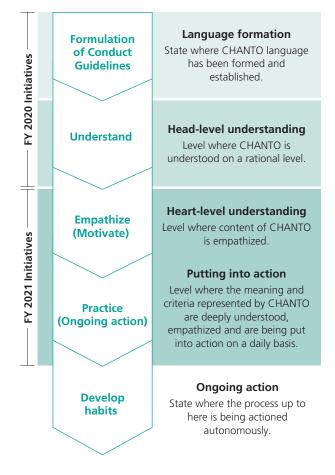
- 1. Goal-oriented, take as one's own issues, and follow through
- 2. Show courage to meet challenges
- 3. Self-disciplined, independent and exert individual abilities
- 4. Respect each other and collaborate with peers
- 5. Continue to cherish diligence and integrity

In fiscal 2020, we held training sessions on understanding CHANTO and the importance of our mission, targeting navigators\* selected from each workplace. These navigators then took the lead in sharing CHANTO at each workplace, and, as a result, employees gained an understanding of CHANTO. In fiscal 2021, we are aiming to deepen their understanding of the meaning of CHANTO, while moving forward with initiatives targeting ongoing action and the

development of habits that enable employees to implement CHANTO. Meanwhile, we are progressing with rolling out this initiative to domestic and overseas Group companies.

\* Employees selected with the criteria that they are non-managerial staff, exhibit leadership, and seem able to draw in their colleagues in a fun way.

#### **CHANTO Fiscal 2021 Goals**



# Training and development of employees

Material issues

# Fostering of leaders and training of globally-minded human resources

#### Fostering the next generation of leaders

We established the DSP Academy in July 2016, which is a career grade-specific selective education and 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. The Academy's programs consist of A1 course, A2 course, A3 course and the Management course. In the five years between fiscal 2016 and fiscal 2020, 397

### Basic Policy II Building of flexible and efficient organization

students completed the program.

Since April 2020, due to the impact of COVID-19, all training has been moved to an online format. Training content relevant to our current era and the changes taking place was also incorporated, such as switching to lessons that instruct participants on proposing and executing business models for the digital age.

The HR Strategy Meeting, which has been held on an ongoing basis since 2008, 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, as well as executive directors of divisions as necessary, has been held regularly with over one hundred meetings during the past ten years. In addition, important personnel-related issues are discussed from time to time, such as work style innovation and diversity & inclusion.

# Promotion of English proficiency enhancement toward globalization

We are working to foster global human resources that can undertake business management overseas in future such as by dispatching personnel to overseas subsidiaries and overseas academic and research institutions.

Also, in addition to selective English proficiency enhancement training of personnel recommended by each department, in fiscal 2020, we adopted the goFLUENT program, which is an e-learning approach to English education, from the perspective of raising the base level of English proficiency company-wide. Similarly, we increased the number of times we offer the TOEIC test from two to four times per year and incorporated TOEIC scores as one of the criteria for applicants applying to sit exams for certain managerial positions.

Going forward, we must increase our pool of employees able to work in a global setting, so we will polish our programs for enhancing English proficiency and will review and implement new programs as well.

# Fostering a corporate culture that encourages self-disciplined and independent career development

#### Strategic allocation of human resources through talent management and acceleration of human resources development

We have adopted and are operating a talent management system to systematically understand and supervise the skills, assets, and capacities of our employees. 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.

In fiscal 2020, we undertook people analytics (workforce analytics) leveraging the information accumulated, including searching and identifying factors that encourage employee growth and factors that contribute to employee engagement.

Going forward, we will continue to implement HR policies and initiatives aimed at both accelerating employee growth by utilizing gathered data, and maximizing results for the organization.

#### KPIs

- Number of participants in selective training Measures how many employees each year are provided with opportunities to acquire the knowledge necessary for upper-level positions.
- Number of employees with overseas work experience Measures how many employees to date have had direct involvement with our global business, and how many employees will be able to support the global business going forward.
- Number of participants in programs to enhance English proficiency Measures how many employees are engaged in self-improvement relevant to globalization.

• Number of cases and applicants utilizing internal job posting system Measures how many opportunities the Company is offering employees and how many employees are

- Number of career consultation
- Measures the level of contribution that consulting provides as part of employee career development.
- Please see page 12 for trends in the number of participants in selective training and of employees with overseas work experience.

#### **Diversity & Inclusion**

#### **Material issues**

# Promotion of active participation by female employees

We believe every employee, regardless of their gender or any other characteristics, being able to perform at their full

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rial issues Sumitomo Dainippon Pharma has set targets and KPIs, and we have provided a list of them on pages 25–26.

potential is vital to achieving our Corporate Mission. Going forward, we believe that an equal ratio of men and women among our employees and among our managerial staff is one yardstick. Moreover, we are aiming to increase the number of female employees returning to and continuing work after a life event such as marriage or giving birth and to increase the number of females selected for managerial positions. The ratio of female managers is steadily increasing, which, among others, is evident in the early achievement, in April 2019, of the goal of at least 10% female managerial staff by fiscal 2020.

Since January 2021, we have maintained the 10% ratio of female managerial staff and are progressing efforts to nurture such staff including training of female leaders with the goal of at least 15% of female senior employees (excluding managers), who are candidates for managers.

Additionally, we are aiming for a work environment where it is easier for each employee to achieve a positive work-life balance. To this end, we have set a goal of—and are working towards—100% of male employees taking childcare leave.





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

#### **Promotion of LGBTQ understanding**

Sumitomo Dainippon Pharma clearly states in our Compliance Standard that we do not discriminate on grounds of sexual orientation and gender identity. We are undertaking measures such as the Ally initiative and providing training for all employees to promote understanding of LGBTQ (lesbian, gay, bisexual, transgender, questioning, and queer).

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 work with Pride

for weddings and funerals, and other programs. These initiatives have been recognized and obtained bronze certification in the Pride Index 2020.



# Promotion of active participation by people with disabilities through appropriate placement

Cocowork Co. Ltd., which was established to support independence of people with mental disabilities and accredited as a special subsidiary, uses solar-powered hydroponics to cultivate leafy vegetables. We have also set up massage rooms at our head offices in Tokyo and Osaka, and employ people with disabilities who hold a masseur license (a national qualification). Additionally, our ratio of employees with disabilities was 2.34% as of June 1, 2021.



Cocowork Esaka Farm (Suita, Osaka)

#### KPIs

- Percentage of female managers (maintain at least 10%)
- Percentage of female senior employees, excluding female managers (by 15% by April 2023) Measures the number of female employees—from a small pool of female senior employees as manager candidates—who, after fulfilling their potential, are promoted to higher positions in each workplace.
- Percentage of male employees taking childcare leave (100%)

Measured as an indicator for how easy it is to achieve a work-life balance in a workplace regardless of the characteristics (such as gender) of the employee.

- Number of participants in e-learning on LGBTQ Measures how many employees are increasing the depth of their understanding of LGBTQ each year.
- Number of Ally activities Measures how many initiatives there are that provide opportunities to support LGBTQ employees.
- Average length of employment of employees with disabilities

Since establishing the right work environment is important for allowing people with disabilities to continue contributing their skills, this measures the average length of employment of employees with disabilities at the Company in order to indicate whether our environment is conducive to including people with disabilities.

Please see page 12 for trends of percentage of female managers, female senior employees excluding female managers, and of male employees taking childcare leave.

# Basic Policy II Building of flexible and efficient organization

#### Message from the Executive Officer in charge of human resources



#### Atsuko Higuchi Executive Officer

Corporate Governance; Corporate Communications; Human Resources

# Success of various measures speeding up organizational rebuilding

In regard to measures for the company organization and human resources I am in charge of, I recognize we have made steady progress over the past three years.

The first area where we have made progress is work style innovation. We have been implementing a variety of measures for some time, but the impact of COVID-19, in particular, has been a great opportunity to think about our workstyles. I believe that each and every one of us is now able to work, thinking autonomously about more appropriate ways of working without being bound by the conventional ways. I would like to promote even greater advancements in workstyles for the COVID-19 pandemic period through to the post-COVID-19 world.

The second area is fostering employees who are willing to take

on challenges. We have seen success stories of employees who have actually been promoted or started new challenges after completing the DSP Academy, the selective education and training program we launched in 2016. I really feel that the selective aspect of the training has led to a positive attitude toward challenges. In recent years, we have also started initiatives to allow employees to design their own careers and request transfer to the department of their choice through the internal job posting system.

The third area of progress is diversity & inclusion. In terms of promoting active female participation, one of our nine directors and three of our 11 executive officers were women as of June 2021. We also achieved our target female manager ratio ahead of schedule, and this ratio stood at 14.6% as of April 2021. In the future, we believe that an equal ratio of men and women among our employees and among our managerial staff should be one of our yardsticks for active female participation. I joined the

Company as a researcher and became an executive officer after serving in corporate planning, public relations, and international business. Compared to those days, I think that female managers are becoming more common in the minds of employees in a positive sense. In manager promotion interviews, I feel strongly that there are many employees, both male and female, who want to demonstrate their abilities in positions of responsibility.

# Positioning human resources as the most important capital

Sumitomo Dainippon Pharma holds the HR Strategy Meeting with all the directors and some of the executive officers, as well as executive directors of divisions as necessary. At these meetings, we monitor our human resources strategy appropriately by discussing the alignment of our human resource policies with our business strategy and the selection and development of the next generation of leaders.

Of the Group's three strengths, research and development and global platform would not be possible without human resources to implement them. In this regard, we will continue to promote the creation of workplaces where employees can reach their full potential, based on the awareness that the most important capital for the Group is its human resources.

#### **Basic Policy I**

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#### **Digital transformation**

We will make strategic use of digital technology to reinforce the organizational base. Our goal is to leverage digital transformation to build an agile organization and human resources capable of spotting

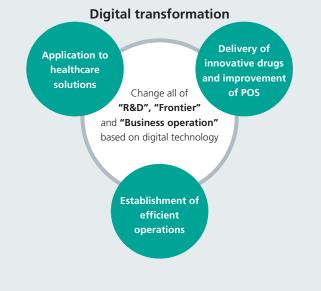
#### Further focus on digital capability:

- Improve company-wide digital capability
- Enhance digital skills and change mindset
- Acquire and develop digital talents
- Enhance platform for data utilization, etc.

Company-wide efforts to identify opportunities leveraging digital technology and deliver best performance:

- Create new value in Pharmaceutical and Frontier areas, mainly led by current business function
- Accelerate company-wide initiatives for operational reform with potential advanced digital technology, mainly led by digital transformation functions

changes in the external environment and acting to address these changes proactively, and flexibly. Through this approach, we simultaneously create new value and bringing about operational reform.



#### Digital transformation strategy

In the Mid-term Business Plan 2022, Sumitomo Dainippon Pharma highlights the pursuit of digital transformation (DX) as a key initiative to re-build the business foundation through "establishment of growth engines" and "building a flexible and efficient organization." Through the formation of a DX promotion system that integrates information technology and digital technology, Sumitomo Dainippon Pharma Group can achieve prompt decision-making throughout the organization. Also, we have been working to develop digital workplaces and to raise Sumitomo Dainippon Pharma Group's digital literacy (skills) and "digital-first" mindset.

Through the strategic alliance with Roivant Sciences completed in December 2019, we acquired two healthcare technology platforms, DrugOME and Digital Innovation, further accelerating the Group's DX efforts and talent pipeline. Through these systems, technologies, and human resources, we can set quantitative goals linked to sales and R&D milestones. This will allow us to increase the probability of success of drug discovery, shorten the development time, and ensure stable manufacturing to deliver safer and more reliable pharmaceutical products. In doing so, we will deliver unique value to a broader range of people, including healthcare professionals as well as patients and their family members, while creating innovative pharmaceuticals and healthcare solutions.

By accelerating DX with a focus on creating and enhancing our business value, we are realizing sustained growth through "transformation into a data-driven pharmaceutical company" and "creation of new value and operational reform."

### Basic Policy II Building of flexible and efficient organization

#### **Promotion system**

Under the lead of Dan Rothman, Chief Digital Officer (CDO) of the Group, we have assembled a team from IT-related departments of the Group companies to form the Digital Transformation Leadership Team in an effort to expedite DX throughout the Group. Also, we have established organizations specialized in DX, such as the Global Data Design Office, the IT Management & Digital Transformation, Frontier Business Office, and MarTech Strategy Office.

Further, to ensure quick and flexible decisions on DX projects, we have established a Digital Transformation Committee in Japan comprised of the Global Data Design Office, Global Corporate Strategy, IT Management & Digital Transformation. We have also established the company-wide working group to promote Al and Data utilization, which consists of representatives from each department in the Company and are working across the organization.

It is under this framework that we are introducing DX to the Group's advanced technologies. At the same time, we have built an agile organization capable of flexibly addressing changes and combining various functions both from within and outside of the Group, while fostering a corporate culture that encourages employees to change and act flexibly and develops such human resources.

#### **Overview of the DrugOME**

DrugOME is a system that leverages diverse data points to promptly deliver quality solutions to varying business issues. The DrugOME team consists of data scientists with advanced expertise in computational research and capabilities. The team communicates and works closely with broader business teams to solve for issues or drive capabilities. We are promoting the use of DrugOME in various situations in our value chain, such as evaluating the feasibility of development compounds using real-world data, optimizing development plan and clinical study designs, making clinical studies more efficient (selection of facilities and recruiting patients), and early acquisition of promising pipelines.

#### **Overview of Digital Innovation**

Digital Innovation is a system that uses digital processes to solve for various issues faced in business activities in the value chain and improve operational efficiency. The Digital Innovation team assigns a Digital Innovators to business teams in order to listen directly to the needs within the company and develop or offer new applications or automation technologies that in turn can drive business value. The Group companies use a common platform thus applications developed by Digital Innovators can be shared seamlessly between departments. Through this process, our Group's digital capabilities will be further strengthened and operational reform will be accelerated.

In Japan, we are developing applications such as search tools for pharmaceutical affairs information as well as support tools for writing documents on clinical studies. In the U.S., we are using tools for predicting and analyzing whether or not a subject will enter a clinical study, and developing an integrated platform that enhances the searchability of drug discovery-related information.

#### Accelerating operational reform

To facilitate the provision of innovative pharmaceuticals and healthcare solutions, we are advancing operational reform based on a transformation to an agile and data-driven corporate culture in addition to strengthening digitally-capable human resources.

We are working on developing human resources, like DX human resources training, data scientist training, fostering of human resources for DX planning, and recruiting citizen developers. We are also working on introducing an agile work style. As for an environment to support our operational reform, we have developed and expanded a communications infrastructure and introduced web-conferencing system so that all of our 3,000 employees can work from home and can perform their job responsibilities, communicating with each other as they were in the office.

To assist collaboration between those working from home, we are advancing a digital workplace for general work by providing a variety of tools, such as electronic white boards for discussing meeting agendas or brainstorming together to incubate new ideas, mind maps for visualizing creative thinking, fresh ideas, and the flow of information, and tools for checking work status and schedules.

#### Basic Policy I

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 Flexible and efficient organization and operations

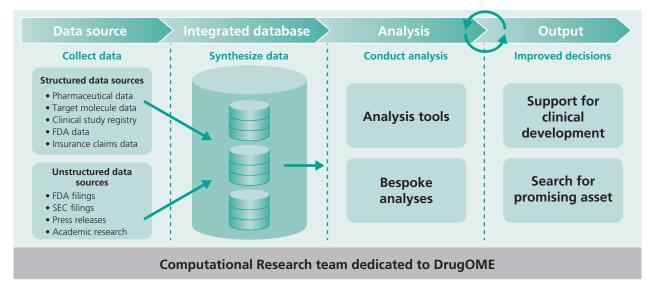
 Corporate culture and talent to drive innovation
 Digital transformation

#### **Promotion system**

	President					
Sumitomo Da	inippon Pharr	na			Chief Digital Officer	
		Digital Ti	ransformation C	ommittee		
Sales & Marketing Division MarTech Strategy Office	Frontier Business Office (FBO)	Strategy	IT Management & Digital Transformation (IDT)	Global Data Design Office (GDD)	Digital Team of Sumitovant Biopharma, In Digital Strategy Digital Innovation Enterprise Technology	c.
Working Group to promote AI and Data utilization Drug Research Division, Drug Development Division, Technology Research & Development Division, Manufacturing Division, Corporate Regulatory Compliance & Quality Assurance Division, Sales & Marketing Division, and Corporate Department		on	Sunovion Pharmaceuticals Inc Sumitomo Dainippon Pharma Oncolo Myovant Sciences Ltd.* Urovant Sciences Ltd. Enzyvant Therapeutics Ltd. Altavant Sciences Ltd. Spirovant Sciences Ltd.			

\* Myovant is a consolidated subsidiary of Sumitomo Dainippon Pharma Group and the Group owns approximately 53% of the outstanding shares of Myovant.

#### **Overview of the DrugOME**



#### **Overview of Digital Innovation**

Digital Innovators	Identifying issues and	Application	Horizontal deployment
	proposing solutions	implementation	of solutions
<ul> <li>Dedicated team of technologists (Digital Innovators) with strong coding and data analytics skills</li> <li>Use standardized system infrastructure (common development platform)</li> </ul>	<ul> <li>Digital Innovators are embedded in business teams</li> <li>They identify operational issues and propose solutions that use digital technologies by working as one with business team</li> </ul>	• Digital Innovators play a central role by agilely developing the solutions and offering them necessary for improving efficiency and solving issues in business teams	<ul> <li>Quickly deploy solutions horizontally across departments with similar operational issues</li> </ul>

### Basic Policy II Building of flexible and efficient organization

Furthermore, by introducing a workflow system and robotic process automation (RPA) technology to the application of documents and routine tasks, respectively, and proceeding with the automation of management work, we have achieved prompt decision-making and higher efficiency and standardization of work processes. Any surplus time thus gained is being allocated to high-value-added work to increase productivity.

# Example applications: creating value through integrating business teams and the IT team

We are attempting to create a brand new business system by inspiring our employees to change the way they think and act by integrating business acumen and IT knowledge.

# Data-driven drug discovery research using in silico drug discovery technology

We aim to enhance the probability of successful research and development for drug discovery by feeding knowledge gained from analysis results of patients' medical and healthcare data back to translational research, in addition to using computers to discover promising compounds. For toxicity and pharmacokinetics assessment, by leveraging artificial intelligence (AI) developed in-house we produce predicted results in a computer before conducting experiments and promising compounds are synthesized or evaluated, increasing efficiency. From the viewpoint of compound synthesis, the use of in silico drug discovery technology has become very common in the past 1-2 years and drug discovery can be done guickly and inexpensively. We believe that in silico drug discovery has increased efficiency 20-30 percent in both development cost and time compared to average when proceeding with conventional drug research.

#### Improving efficiency of non-clinical studies with AI

After carefully picking promising compounds out of many new ones, we conduct non-clinical studies to verify their efficacy and safety. In the past, we observed changes in cells and behaviors of animals for a long time to detect any activities. To proceed experiments efficiently, the detection system using machine learning technology changed all this. The lengthy verification process has been shortened significantly, allowing us to complete the analysis of experimental results quickly and move on to the next phase.

#### DX of the frontier business

We are working on launching the frontier business early with a view toward realizing "wide-ranging well-being and diverse lifestyles" through the provision of never-before-seen healthcare solutions to social issues in the healthcare areas other than pharmaceutical products, such as digital therapeutics (DTx).

In designing and providing flexible, effective, and caring solutions that accurately capture latent issues shared by all, including healthy individuals with presymptomatic diseases, caregivers, guardians, and healthcare professionals, as well as patients, DX is not a mere tool but counted as a critical driver. For the frontier business, we will expedite the introduction of innovative DX technologies and joint research and development projects with many partner businesses, with social implementation and commercialization of healthcare solutions in mind.

➡ Please see page 46 for details of the frontier business.

#### Supporting information provision by MRs

On the sales front in Japan, we are accelerating data-driven DX while introducing AI, virtual reality (VR), and other digital technologies to traditional information provision by medical representatives (MRs).

We are seeking to establish a new sales style as we take advantage of a variety of digital technologies by, for example, building a product demand prediction model using AI, conducting advanced analysis and simulation of data gained from sales and marketing activities, and developing desk work automation tools for MRs using the latest programming technology.

#### Basic Policy I

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#### Sumitomo Dainippon Pharma included in "Noteworthy DX Companies"

In fiscal 2020, we were selected among "Noteworthy DX Companies" based on the findings of the "2020 Survey on Digital Transformation," which was jointly conducted by the Ministry of Economy, Trade and Industry of Japan (METI) and the Tokyo Stock Exchange (TSE). We received this accolade in recognition of our extensive efforts in this regard, including the development of a DX promotion system that achieves the integration of IT and digital technology and the Head Office and each department and quick decision-making, the raising of the overall level of ability and mindset to make the most of DX, and the development and provision of AI and data utilization platforms. In fiscal 2021, we were once again selected among "Noteworthy DX Companies" and recognized as a "Digital Transformation Certified Business Operator" under the digital transformation certification initiative by the METI.

#### Message from the CDO



Dan Rothman Chief Information Officer of Sumitovant and Chief Digital Officer of Sumitomo Dainippon Pharma Group

# Digital transformation will speed the pace of innovation

With DX, we are trying to transform the way we do business faster and more effectively. We believe that we can maximize the value we deliver to patients and shareholders by using DX technology as the basis of our business operations.

My areas of focus as Chief Digital Officer are improving communication and transparency and automating many of the manual administrative tasks.

With the sharing of new innovations quickly from one team to another, new ideas can be put into action quickly instead of undergoing lengthy reviews and analyses. With this model, we can use technology to its full advantage across our business: from scaling drug discovery and accelerating clinical studies, to optimizing our commercial launches and business processes.

#### **Kakushin and Trust**

Business transformation never comes about with the introduction of new technologies alone, but always comes from both technology and people.

Trust is the component that will make this work. As technologists, scientists and executives, we must fully trust one another as we digitally transform our enterprise to get more treatments to more patients.

In Japanese, the term *kakushin* means "transformation," which is about change. The term also means "innovation," which indicates improvement through new ideas. We keep both of these important concepts in mind as we acceralate to achieve digital transformation.

Through collaboration between the business teams and the IT team, we will achieve our goal of creating value and providing patients with innovative treatments as quickly as possible.

# Environment

#### **Environmental management**

Environmental issues such as climate change are serious global problems that threaten the health and wellbeing of people worldwide. Our environmental initiatives through our business activities will contribute to solving these issues, and by evaluating and appropriately responding to the impact of risks and opportunities on our business, we will contribute to achieving a sustainable society, which will lead to the sustained enhancement of corporate value.

Under our Basic Environmental Policies, Sumitomo Dainippon Pharma formulates medium- to long-term environmental goals and medium-term environmental plans and annual implementation plans. Meanwhile, we evaluate such initiatives at the Environmental and Safety Committee. In fiscal 2020, the Environmental and Safety Committee and Management Committee discussed the stance we ought to take as a company, and the Board of Directors in May 2021 decided to revise the Basic Environmental Policies. This revision clarifies the proactive disclosure of environmental information, the promotion of dialogue with stakeholders, and our stance undertaking initiatives over our entire value chain.

Priority issues	Objectives	Results	Explanation		
Building a low-carbon society	<ul> <li>Climate change measures</li> <li>1. Reduce CO2 emissions by 23% from FY2005 level by FY2020</li> <li>2. Improve per-unit CO2 emissions by 1% or more per year</li> <li>Energy Saving Measures</li> <li>3. Improve per-unit energy consumption by 1% or more per year</li> </ul>	1. ✓ 2. ✓ 3. ✓	<ol> <li>34% reduction from FY2005 level Reason: Contribution of reorganization into two plants at the end of March 2019, in addition to capital investment in energy conservation and CO<sub>2</sub> reductions (including upgrading to hig efficiency equipment and installation of LED lighting) and measures to conserve energy and save electricity in summer and winter.</li> <li>1.4% improvement on previous fiscal year</li> <li>1.4% improvement on previous fiscal year Reason: Contribution of improvements in energy efficiency and associated improvement in per-unit CO<sub>2</sub> emissions</li> </ol>		
Establishment of a sound material-cycle society	<ol> <li>Maintain final landfill disposal at less than 1% of waste generated</li> <li>Reduce waste generated by about 25% from FY2010 level in FY2020</li> <li>Maintain the recycling rate to 80% or more</li> </ol>	1. ✔ 2. X 3. ━	<ol> <li>Final disposal rate: 0.7% Reason: Proactive renewal to non-landfill disposal outsourcing contracts</li> <li>Decreased by 14% from FY2010 level Reason: Greater than expected increase in production compared to that envisaged at time of goal setting</li> <li>Recycling rate: 79.8% (however both FY2018 and FY2019 achieved the goal with 83%) Reason: Reduction in generation amount of waste oil with a high recycling rate in FY2020, mainly due to decrease in production volume of active pharmaceutical ingredients (APIs) for MEROPEN<sup>®</sup></li> </ol>		
Biodiversity conservation	Effective Use of Water Resources Reduce water consumption by about 20% from FY2010 level in FY2020	~	Reduced by 35% from FY2010 level Reason: Contribution of reorganization into two plants at the end of March 2019, in addition to changing the number of times certain facilities were washed with water.		
Chemical substances management Maintain atmospheric release rate at less than 1% of the volume of Pollutant Release and Transfer Register (PRTR) substances and volatile organic compounds (VOC) substances handled		<b>V</b>	PRTR substances handled: 0.3% VOC substances handled: 0.7% Reason: Reduced atmospheric release due to installation of equipment to recover toxic chemical substances		
Environmental communications	<ol> <li>Promote communication with stakeholders</li> <li>Promote communication with Group Companies</li> <li>Enhance environmental education</li> </ol>	1. ✓ 2. ✓ 3. ✓	<ol> <li>Obtained third party assurance to enhance the reliability of disclosed information; obtained A- rating for climate change and B rating for water security from the Carbon Disclosure Project (CDP; FY2020); held ESG meetings</li> <li>Implemented EHS inspections, held meetings for exchange of environmental safety information between domestic Group companies</li> <li>Held training for new employees and e-learning for all employees during Environment Month</li> </ol>		

Results and explanation of Mid-term Environmental Goals (fiscal 2020 goals) 🗸 Achieved 😑 Not achieved by slight margin 🗙 Not achieved

#### **Revision of Basic Environmental Policies**

The decision to revise our Basic Environmental Policies was made in the Board of Directors meeting held on 12 May 2021. For further details, please see:

#### https://www.ds-pharma.com/csr/environment/policy.html

#### Mid- to long-term environmental goals

We have set the following mid- to long-term environmental goals to achieve a sustainable society.

# Long-term environmental goals (targeting fiscal 2030 and fiscal 2050)

- Reduce our greenhouse gas (GHG) emissions (scopes 1 and 2) by 35% from fiscal 2017 level by fiscal 2030, and aim to achieve net-zero emissions by fiscal 2050.
- Reduce water withdrawal by 12% from fiscal 2018 level by fiscal 2030.
- Maintain recycling rate at 80% or higher and aim for at least 85% by fiscal 2030.
- Maintain final disposal rate at less than 1% and aim for less than 0.5% by fiscal 2030.

#### **Mid-term Environmental Goals**

Please see our website for our Mid-term Environmental Goals (fiscal 2021 – fiscal 2023).

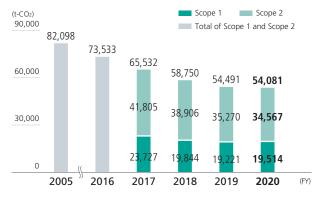
https://www.ds-pharma.com/csr/environment/burden.html The results of our fiscal 2020 Mid-term Environmental Goals are outlined in the table on page 59.

#### **Building a low-carbon society**

We have agreed with the Science Based Targets initiative (SBTi) that promotes the setting of GHG reduction targets in alignment with the Paris Agreement, and have formulated our GHG reduction targets for up to fiscal 2030 aligned with the well-below 2°C (WB-2°C) level set in the SBTi. Each year, we take applications from worksites for capital investment in energy conservation and CO<sub>2</sub> emission reductions and have been systematically introducing LED lighting and more energy-efficient equipment based on considerations such as the cost effectiveness (yen/t-CO<sub>2</sub>) of CO<sub>2</sub> emission reductions and investment payback periods.

In August 2021, we also replaced most of the city gas used in cogeneration systems and others at the Suzuka Plant with carbon-neutral city gas supplied by Toho Gas Co., Ltd. (volume: 5,000 thousand m<sup>3</sup>/year, period: 2 years, 8 months) in order to contribute to reducing global GHG emissions and promote various environmental conservation projects around the world.

#### CO<sub>2</sub> emission trends

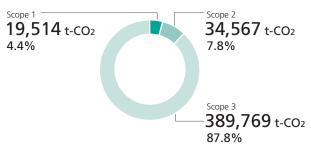


The fiscal 2019 figures for Scope 1 and Total of Scope 1 and Scope 2 have been changed to improve accuracy.

Sumitomo Dainippon Pharma supports Japan's Carbon Neutral Declaration and aims to reduce GHG emissions to net-zero (Scope 1 + 2) by fiscal 2050 by proactively adopting energy-saving and emissions-reducing technologies, which are expected to advance in the future, as well as renewable energy, the use of which is expected to become widespread, to achieve decarbonization.

We are also working to calculate greenhouse gas emissions across the supply chain and plan to implement initiatives to reduce GHG emissions across our value chain going forward.

#### Fiscal 2020 CO2 emissions by scope



#### KPIs

# • Implementation of measures to achieve FY2030 and FY2050 goals

To achieve the long-term goals, we will consider and implement specific measures, such as continuous investment in equipment to reduce CO<sub>2</sub> emissions as well as promoting a switch to renewable energy.

• Per-unit energy consumption To achieve more efficient use of energy, we will verify

improvements in per-unit energy consumption.

#### **Environment**

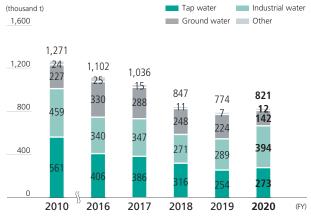
#### Effective use of resources (water and waste)

#### Effective use of water resources

Ensuring the quality and sufficient amount of fresh water is essential for our manufacturing and other business activities. We are working to reduce water withdrawal with an aim of utilizing water resources effectively and reducing environmental impact.

We have already taken measures, which include reviewing washing frequency at some production facilities and installing water-saving nozzles on faucets for washing in animal breeding facilities. We will continue to make water use more efficient and take measures to save water to reduce water withdrawal.

#### Water withdrawal by source



As some of the tap water and other water withdrawal at one facility had not been counted, the amounts of tap water and other water withdrawal for FY2010 and FY2016 - 2018 have been adjusted retroactively. As a result, the amounts differ from the amounts stated in previous Integrated Reports.

#### KPIs

• Implementation of measures to achieve FY2030 goals To achieve the goal for fiscal 2030, which is the reduction of water withdrawal, we will implement concrete measures, including expanding existing measures to other sites and considering and selecting new measures to reduce water withdrawal.

#### **Reduction of waste**

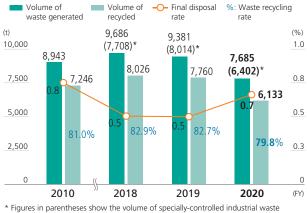
To make effective use of limited resources, Sumitomo Dainippon Pharma strives to actively practice the "3Rs" of waste management (reduce, reuse, recycle).

Going forward, we will continue to promote recycling through the active pursuit of thorough waste separation and consignment of recyclable waste to waste recyclers.

In addition, marine plastic waste has been recognized

as a new environmental problem in recent years. As part of our efforts to eliminate plastic bottles, we are promoting their replacement with environmentally friendly containers and products, including metal bottles and canned beverages, in the vending machines we install and manage at our business facilities. Furthermore, to encourage recycling of waste plastic, we plan to formulate goals that will contribute to recycling of plastic resources.

#### Waste-related indicators



generated out of the volume of waste generated

#### KPIs

• Recycling rate and final disposal rate of waste We will verify the recycling rate and final disposal rate of waste as an indicator to measure the progress of efforts to promote recycling and avoid final disposal of waste as much as possible.

#### Proper information disclosure and response to TCFD

#### Identifying risks and opportunities

In order to support the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD), we are working to analyze, evaluate, conduct concrete initiatives and disclose information concerning climate change and water related risks and opportunities according to the recommendations, under our risk management system. With regard to water risk in particular, we have implemented surveys of risks related to current and future water supply and demand at our main business sites and vulnerabilities of downstream environments. In fiscal 2020, we surveyed water related issues that have actually arisen in the past and future region-specific issues.

In future, we will comprehensively analyze and evaluate these results. Moreover, with regard to managing

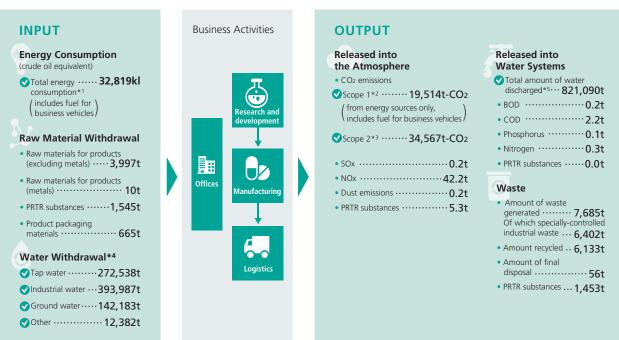
supply chain risks, we continue to evaluate water risks, firstly of raw material manufacturers and manufacturing contractors for our key products, using a water risk atlas, Aqueduct, published by the World Resources Institute.

#### Third-party assurance

#### KPIs

- Promotion of evaluation of risks and opportunities related to climate change and water We will aim for sustained enhancement of corporate value by assessing financial impact and considering the incorporation of the results into management strategy based on the TCFD recommendations.
- Acquisition of third-party assurance for environmental data We will continue to obtain third party assurance to

improve the reliability of environmental data.



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 kl/GJ The unit calorific values and the types of fuel to be calculated are based on "Act on the Rational Use of Energy."
- \*2 Fuel consumption × fuel unit calorific value × fuel CO<sub>2</sub> emissions factor
- The unit calorific values and CO<sub>2</sub> 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 CO<sub>2</sub> emissions factor#1 + purchased heat × heat CO<sub>2</sub> emissions factor#2
  - (Note) #1 The value (0.33 t-CO<sub>2</sub> / thousand kWh) which The Federation of Pharmaceutical Manufacturers' Associations of JAPAN has adopted to manage the progress of its CO<sub>2</sub> 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.

#### Overview of environmental impact (FY2020)

#### **Environment**



#### **Contribution to Societies**

# **Contribution to societies**

Material issues Sumitomo Dainippon Pharma has set targets and KPIs, and we have provided a list of them on pages 25–26.

#### Contribution to global health

Material issues

**Development of drugs to treat malaria and antimicrobial-resistant (AMR) bacterial infections** Expectations of pharmaceutical companies are rising amid the COVID-19 pandemic and other pressing issues around international healthcare sustainability.

Sumitomo Dainippon Pharma is working to solve issues through research in the area of infectious diseases which pose an international threat such as malaria and antimicrobial-resistant (AMR) bacterial infections. We believe that these efforts will not only contribute to the achievement of the SDGs, but will also increase our presence as a global pharmaceutical company.

In a major initiative, the preclinical development project for a new pre-erythrocytic malaria vaccine, a three-way collaboration between Ehime University, Sumitomo Dainippon Pharma, and PATH of the United States, was selected for a grant by the Global Health Innovative Technology Fund (the GHIT Fund) in March 2021. It is the third consecutive year that our projects have been selected following the GHIT Fund grants for joint research into an asexual blood-stage vaccine and a transmission-blocking vaccine being implemented by Ehime University and Sumitomo Dainippon Pharma. Successful completion of the project will advance development toward achievement of a comprehensive malaria infection, onset, and transmission-blocking vaccine. We have also been making recommendations for improvement of the research and policy environment to accelerate vaccine development and supply through dialogue with the League of Legislators to Eliminate Malaria by 2030, which was established in March 2021.

# Strengthening of public-private collaboration on countermeasures against AMR and appropriate use of antibiotics

Since June 2019, we had been working with 31 doctors and pharmacists at ten hospitals in Vietnam to implement drug susceptibility surveillance research aimed at the appropriate use of antibiotics and countermeasures to antimicrobial resistance (AMR). Analysis of the research data was completed in August 2020, and we are providing a detailed report and exchanging opinions with each hospital with the aim of further spreading 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.

# Promotion of public awareness-raising activities for health, hygiene, and nutrition

Sumitomo Dainippon Pharma provides an NPO-led health improvement program for mothers and children in Cambodia's Kampong Cham Province. In fiscal 2020, the program displayed awareness-raising posters and pamphlets on integrated management of childhood diseases, child nutrition and hygiene, including COVID-19 prevention measures, in local hospitals, health centers, markets and municipal buildings, and distributed them through health district offices and health centers, mainly to expectant mothers and mothers with children under five years old.

#### KPIs

• Progress of development in infectious diseases area —Number of projects

—**Number of products (number of products launched)** The number of projects and number of products (number of products launched) will be used as indicators to measure the progress of development and the Company's contribution in the infectious diseases area.

• Number of policy recommendations in infectious diseases area

The number of policy recommendations will be set as an indicator to make further improvements in the environment in the infectious diseases area, which will promote research and development in the area.

• Number of doctors and pharmacists who participated in the AMR countermeasure support program

The number of participants in support programs to help healthcare professionals will be used as an indicator in efforts to further promote public awareness.

• Number of local residents assisted by maternal and child health programs in developing countries We will promote public awareness around health, hygiene, and nutrition by providing assistance to more local residents through our programs.

# Initiatives to improve access to medicines

Even with today's advances in medicine, there are still many unmet medical needs, and an R&D-oriented pharmaceutical company has a mission to solve this issue. In addition, there are parts of the world where it is difficult for all people to receive equal access to necessary healthcare due to inadequate medical systems and poverty.

In addition to research and development of products,

**Material issues** 

#### **Contribution to Societies**

Sumitomo Dainippon Pharma works to solve issues related to healthcare access by raising public awareness of health, hygiene, and nutrition in collaboration with international organizations, government agencies, research institutions, and civil society.

As part of these efforts, since 2017 Sumitomo Dainippon Pharma has been participating in the Access Accelerated partnership initiative by organizations around the world, including global pharmaceutical companies, City Cancer Challenge, and PATH. 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 improvements in access to pharmaceuticals, even during the COVID-19 pandemic.

# Promotion of public awareness-raising activities with the aim of improving 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. We provide "Kusuri-no-shiori," "Instructional Leaflets," and guidance for patients using our pharmaceuticals and their families to promote appropriate use.

# Response to requests for the development of unapproved and off-label drugs

As an initiative to provide new treatment options in areas with high unmet medical needs, Sumitomo Dainippon Pharma also addresses to requests for development of

#### KPIs

 Number of programs aiming to improve medicine-related literacy

The number of programs implemented will be used as an indicator due to the importance of providing opportunities for people to correctly learn about treatment using medicines and their side effects.

 Number of responses to requests for unapproved and off-label drugs
 The number of responses on unapproved and off-label drugs will be used as an indicator to measure our

contribution to new treatment options.

• Number of policy recommendations by the Company on access to medicines We will also take part in policy recommendations aimed at provision of fairly-priced drugs, leading to regulatory development. unapproved and off-label drugs. Thus far, we have obtained four such approvals, including a conditioning treatment prior to autologous hematopoietic stem cell transplantation for malignant lymphoma in March 2020.

# Improvement of healthcare Material issues infrastructure in developing countries

# Support for capacity building of healthcare professionals, development of healthcare networks, etc.

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. To date, we have trained 57 Community Care volunteers for Mothers and Newborns, who visited the homes of 467 antenatal women and 470 postnatal women in fiscal 2020.

Moreover, in collaboration with the local government, we donated surgical masks and disinfectant solutions to 12 health centers in the province through an NPO with the aim of ensuring the safe operation of the centers, which are the bases for local healthcare.



Home visit by a Community Care volunteers for Mothers and Newborns (Cambodia)

#### KPls

- Number of community care volunteers trained through maternal and child health programs in developing countries
- Number of partnerships working to improve healthcare infrastructure in developing countries We will contribute to improving infrastructure in developing countries by setting the number of specialist human resources trained and the number of partnerships as indicators because securing human resources in healthcare and pharmaceutical deregulation are necessary to improve healthcare infrastructure in developing countries.

Material issues

Raterial issues Sumitomo Dainippon Pharma has set targets and KPIs, and we have provided a list of them on pages 25–26.

#### Patient support and advocacy

# Improving disease-related literacy for patients, their families, and society

#### Holding public lectures

Sumitomo Dainippon Pharma holds public lectures all over Japan not only for patients and their families, but also for the broader general public to promote an accurate understanding of diseases and contribute to solving social issues.

In fiscal 2020, we held seven public lectures on Parkinson's disease, two on diabetes, and one on dementia with Lewy bodies.

Starting in fiscal 2021, we will conduct questionnaires on the level of understanding and satisfaction with the lectures, which will be reflected in the content.

# Working with patient advocacy groups (including donations)

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

#### Main donations in fiscal 2020

#### 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

#### Advancing patient advocacy in the U.S.

Sunovion Pharmaceuticals Inc., our U.S. subsidiary, joined the global community in recognizing Parkinson's Disease Awareness Month with the goal of raising awareness and promoting education about Parkinson's Disease (PD) in April. Employees were encouraged to celebrate World



Parkinson's Day on April 11 and wear a red shirt representing the Parkinson's tulip symbol or a silver shirt symbolizing the Parkinson's ribbon. In addition, they

The symbol for Parkinson's Disease Awareness Month in April participated in the Parkinson's Foundation National Moving Day USA Virtual Event and the annual Parkinson's Unity Walk (the largest single-day grassroots fundraiser for PD research) on April 24.

# Raising disease awareness and providing information through websites and SNS

We work with patient groups to create and publish websites aimed at providing information for patients and their families and raising disease awareness among the general public. In fiscal 2020, we also set up official accounts on YouTube and Facebook to diversify and enhance our channels for dissemination of information.

The purpose of *Kokoro Share* content is contributing to better treatment and lifestyle by providing accurate and easy-to-understand information on schizophrenia and bipolar disorder for patients and their families.

The content of *Rehabili Kitchen for Parksinson's Disease Patients* on our Parkinson's Disease Station features cooking-themed rehabilitation that can be done at home. The concept of the video is rehabilitation using cooking to increase awareness of each individual movement.



Kokoro Share (Only available in Japanese) https://kokoro-share.jp/



Rehabili Kitchen for Parkinson's Disease Patients (Only available in Japanese) https://healthcare.ds-pharma.jp/disease/parkinson/kitchen/index.html

#### **Contribution to Societies**

#### KPls

- Activities from patient perspective through healthcare professionals
   We will further promote activities from the patient perspective in the provision of information to healthcare professionals by MRs, in addition to our social contribution activities.
- Level of understanding and satisfaction of participants in public lectures The level of understanding and satisfaction of

participants will be used as an indicator to measure how much we are contributing to raising awareness of diseases and solving social issues in the opportunities we have for contact with patients and the general public.

- Number of support activities through donations and cooperation with patients' associations
   We will support the activities of patient groups to increase literacy about diseases.
- Dissemination to raise awareness of diseases through our website The volume of contents that strengthens the raising of awareness about diseases and the provision of information will be used as an indicator as the dissemination of better information to patients and the general public is important for increasing literacy.

#### Local community contribution

#### **Material issues**

# Fulfilling responsibilities and contributing as a member of the community with awareness of harmony with society

# 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 2020, we updated the content to create a new program for senior high school students on the topic of genome analysis. We ran the new program at four schools, and approximately 200 students participated. Through this program, we hope that students will recognize the various and diverse ideas of other people, leading to a deeper understanding of themselves and others. Starting in fiscal 2021, we will not only conduct the lectures, but will also carry surveys on understanding and satisfaction to help us improve the program.

We also participated in the fiscal 2020 SDGs Quest Mirai Koshien\* in the Kansai area as a special co-sponsor following our involvement in the fiscal 2019 event based on our desire to support new ideas of high school students for solving social issues.

We believe that these initiatives will not only stimulate teen's interest and involvement in science and improve the quality of education in the local community, but will also increase trust in the Company and attract talented human resources in the future.

\* SDGs Quest Mirai Koshien: a future-oriented contest in which high school students present SDGs Action ideas that are solutions for a variety of global and social problems, including climate change, energy, biodiversity, gender, water, and more.



"Encouraging Young People to be Repeat Blood Donors," the topic that Kyoto Prefectural Toba High School came up with was selected for the Sumitomo Dainippon Pharma Award.

#### 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 erial issues Sumitomo Dainippon Pharma has set targets and KPIs, and we have provided a list of them on pages 25–26.

Sumitomo Dainippon Pharma, and "Gekkan Karada Column," which takes up such themes as maintaining and improving the health of junior high school students and ways of dealing with physical ailments. In October 2020, we added "Mirai Tsukuro: SDGs Unit" to show the relationship between health and the SDGs and to introduce the activities of this generation and the Company's initiatives related to each of the SDG goals.



https://www.ds-pharma.co.jp/sukoyaka/

Scoppi, the navigator on SUKOYAKA Compass

#### Social contributions and donations

We donate to organizations involved in global health and fostering the next generation, areas we place importance on, by matching donations from officers and employees with corporate donations. In fiscal 2020, we donated to 30 organizations, including four organizations which received these matching donations.

We also participated in READYFOR (crowdfunding) related to COVID-19.

Donation, support, and social contribution activities

 $(https://www.ds-pharma.com/csr/social\_contribution/social\_contribution.html)$ 

# Cooperating in vaccination support work by pharmacist volunteers

Since June 2021, we have been cooperating in vaccination support work carried out by the Osaka Pharmaceutical Association for COVID-19 vaccinations at the Osaka mass vaccination center. Employees who are qualified pharmacists and agree to cooperate in support work at vaccination sites can participate in this activity using the Company's volunteer leave system.

# Building even stronger community contribution activities in North America

Since 2012, Sunovion's "Hands On!" community service

program has engaged employees in volunteer activities that contribute to building stronger communities where they live and work. To date, employees have volunteered more than 32,000 total hours to projects supporting youth and educational programs, health and medical services and community relief initiatives.

During Hands On! 2020, employees pledged to volunteer up to a total of eight hours of service and were allowed to include family members to join in giving back while following COVID-19 safety protocols. As part of their volunteer efforts, employees and family members donated food, clothing and books at locations near their homes, wrote and sent letters to military service members and virtually mentored college students to help them navigate the professional world.



Volunteer activities

#### KPIs

• Number of activities to support the development of the next generation and level of understanding and satisfaction of participants

The level of understanding and satisfaction of participants (students and teachers) will be used as an indicator to measure the contribution of visiting lectures on the topics of bioethics and genome analysis.

- Number of donations for social contribution that lead to resolution of social issues (disasters, people with disabilities, the environment, biodiversity, etc.) We will contribute to solving social issues by supporting organizations involved in global health and education of the next generation, areas the Company places importance on.
- Number of charitable activities in local communities The level of implementation of employee participation-based activities and the number of participants will be used as indicators as it is important for employees to participate and to expand the circle of support.

Message from the Chairman

# Aiming for sustained enhancement of corporate value by strengthening corporate governance

#### Masayo Tada

Member, Board of Directors, Chairman

# Initiatives to enhance the effectiveness of the Board of Directors

Sumitomo Dainippon Pharma regards corporate governance as one of the most important factors for sustained growth and enhancement of corporate value over the medium to long term, and we have been investing considerable efforts into development of rules and systems related to corporate governance. As a part of such efforts, since fiscal 2015 we have evaluated the effectiveness of the Board of Directors. At the end of each fiscal year, a questionnaire survey is conducted with all members of the Board of Directors, including the Outside Directors. Based on an analysis of the results of the questionnaire, the major matters that need to be focused on in the following fiscal year are identified, and efforts are undertaken in cooperation with the executive officers to enhance the effectiveness of the Board of Directors.

In fiscal 2020, based on the evaluation of the analysis of the previous fiscal year, three issues were identified as key challenges and initiatives aimed at addressing them have been carried forward: improvement of discussions for enhancing corporate value in the medium to long term; ideal future composition of the Board of Directors; and further improvement of the quality of deliberations by the Board of Directors—. With regard to the first issue of improvement of discussions for enhancing corporate value in the medium to long term, members of the Board of Directors discussed management issues from a medium- to long-term perspective, in a total of four times. Going forward, a venue will be provided where even deeper discussions can take place.

Regarding the second issue, ideal future composition of the Board of Directors for the future, based on the Company's "Vision for 2033" and other initiatives, the Nomination and Compensation Committee had two discussions to consider the areas of expertise and perspectives required of the members of the Board of Directors. From the aspect of ensuring diversity of the Board of Directors, the appointment of women or members based outside of Japan to the Board of Directors may, for example, be brought up as an issue for discussion; however, the goal must go beyond simply fulfilling a head count to have meaning. Additionally, we understand the importance of training and developing candidates in-house who contribute to realizing diversity for the Board of Directors, while keeping in mind criteria for the ideal candidates of the future.

With regard to the third issue, further improvement of the quality of deliberations by the Board of Directors, efforts were made to enhance explanations for Outside Directors and to not only improve the quality of the materials but also distribute them early, in addition to setting an appropriate amount of time for deliberation according to content of the inquiries.

With these initiatives, which were the result of the evaluation of the effectiveness of the Board of Directors in fiscal 2020, it was confirmed that the effectiveness of the Board of Directors of the Company has been ensured in general. Moreover, based on analysis of the questionnaire survey results, additional key matters were identified to be addressed in fiscal 2021: further enhancement of discussions for risk management; provision of the appropriate number of agenda items and appropriate time for deliberation; and enhancement of training. In this regard, I look forward to continuing our efforts to further improve the functions of the Board of Directors.

# Addressing the revised Corporate Governance Code

Sumitomo Dainippon Pharma has made efforts to realize effective corporate governance, including taking diversity into consideration in the appointment of and increased numbers of Independent Outside Directors.

In June 2021, Japan's Corporate Governance Code was revised for the first time in three years.

These revisions are broadly described in three points. The first point is to fully utilize the functions of the Board of Directors. As mentioned earlier, ongoing efforts are being carried out regarding this matter, with one Independent Outside Director being added to the Board of Directors in fiscal 2021. As a result, the number of Independent Outside Directors now stands at four, with Independent Outside Directors now making up 44 percent of the Board of Directors.

The second point places importance on ensuring the diversity of the Company's core human resources. Aligned with this point, there are three women and two members from outside Japan (one of whom is one of the aforementioned women.), among the executive officers who are members of the Management Committee. Having diverse perspectives at the executive level plays a significant role in decision-making, and I believe this involvement will lead to the nurturing and development of the next generation of talent and leadership to benefit our organization.

The third point places even greater

importance on initiatives concerned with medium- to long-term sustainability, including Environmental, Social, and Governance (ESG) elements. The Company is proactively carrying forward initiatives aimed at improving the sustainability of every aspect of ESG. Particularly with regard to the issue of climate change, which is a pressing issue for all of humanity, it is the policy of the Company to engage in activities to obtain SBT (Science Based Targets) certification, and endorse the TCFD (Task Force on Climate-related Financial Disclosures) proposal, as well as analyze and evaluate risks and opportunities for disclosing information related to the proposal, in order to realize the reduction of greenhouse gas (GHG) emissions (Scope 1+2) to net-zero by fiscal 2050, based on the Basic Environmental Policies, which underwent revision in May 2021.

Besides these three main points, with regard to the group's governance, the revisions also require development of Corporate Governance systems protecting the interests of minority shareholders in listed companies which have a controlling shareholder. As Sumitomo Dainippon Pharma is a listed company which has a parent company, the Supervisory Committee for Conflict of Interests in Transactions between Group Companies established as an advisory body to the Board of Directors in April 2020 and composed of all the Independent Outside Directors, deliberates on material transactions with the parent Company's Group from the perspective of protecting the interests of minority shareholders.

Through these initiatives, Sumitomo Dainippon Pharma pursues the sustained growth and the enhancement of corporate value over the medium to long term by continuously strengthening corporate governance, while taking into consideration the demands made by society on the Company.

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Member, Board of Directors, Chairman



#### **Corporate Governance**

#### **Corporate governance**

Sumitomo Dainippon Pharma commits itself to continuously pursuing the establishment of a corporate governance system which is highly effective, aiming for the fuller realization of our Corporate Mission and Management Mission. The Company posts on its website the summary for its basic concept and basic policy titled the "Basic Policy on Corporate Governance."

The Company will respond appropriately to the June 2021 revisions of the Corporate Governance Code, including the submission of a Corporate Governance Report corresponding to the revisions by December 30, 2021.

#### **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 nine members (including one female Director as of July 1, 2021), including four 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 as its chairperson, and holds meetings as necessary, as a consultative body to the Board of Directors.

The Company has also 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 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.

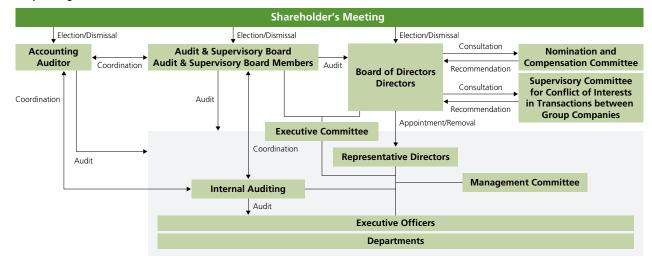
The Executive Committee holds a meeting once a month, in principle, for the purpose of appropriately sharing among the Directors and the Audit & Supervisory Board Members, including the Outside Directors and the Outside Audit & Supervisory Board Members, as well as Executive Officers and other related persons, the status of the execution of business and material matters relating to the execution of business.

#### 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 six members, the majority (four members) of them being Independent Outside Directors as of July 1, 2021, and the chairperson being appointed from among the Independent Outside Directors.

Chairperson	Yutaka Atomi (Outside Director)
Members	Masayo Tada (Director, Chairman) Hiroshi Nomura (Representative Director, President and CEO) Saeko Arai (Outside Director) Nobuhiro Endo (Outside Director) Minoru Usui (Outside Director)

#### Corporate governance structure



# Supervisory Committee for Conflict of Interests in Transactions between Group Companies

The Company set up the Supervisory Committee for Conflict of Interests in Transactions between Group Companies on 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.

Chairperson	Saeko Arai (Outside Director)	
Members	Yutaka Atomi (Outside Director) Nobuhiro Endo (Outside Director) Minoru Usui (Outside Director)	

The Committee meetings were held twice in fiscal 2020. At the first meeting, the Committee appointed the chairperson. At the second meeting, the Committee confirmed that the transaction for the establishment of S-RACMO Co., Ltd., a joint venture between the Company and Sumitomo Chemical, did not pose any problems from the perspective of protecting the interest of the Company's minority shareholders.

### Audit system

The Audit & Supervisory Board consists of five members (including one female Audit & Supervisory Board Member), 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 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.

### Details of non-audit services

The Company delegates to its Accounting Auditor the "preparation of a comfort letter associated with the issuance of corporate bonds" (which is a non-audit service) described in Paragraph 1 of Article 2 of the Certified Public Accountants Act.

### Accounting Audits, Remuneration (FY2020)

	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)	159
Total amount of fees to be paid in cash or otherwise by the Company or Subsidiaries of the Company	162

(Note)

- 2. Under the Audit Agreement between the Company and the Accounting Auditor, there is no distinction between the compensation and the like for an audit under the Companies Act and the Financial Instruments and Exchange Act. Moreover, the two amounts cannot be substantially distinguished from each other. Thus, the amount of compensation and the like related to the audit attestation services reflects the total sum of these two kinds of amounts.
- 3. Significant subsidiaries located overseas were audited by auditing firms other than the Accounting Auditor of the Company.

### Directors

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

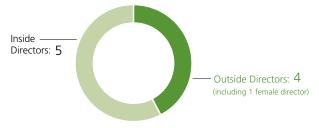
The Audit & Supervisory Board of the Company has determined to consent to the amount of the remuneration and the like for the Accounting Auditor after performing necessary verifications on the details of the Accounting Auditor's audit plan, status of performance of accounting audit duties, and the appropriateness of the basis for calculating the remuneration.

### **Corporate Governance**

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, 2021)



### 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

#### Governance reform: progression of initiatives

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 and holding remote meetings with 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 and holding remote meetings with 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.

### Material issues Corporate governance • Pursuit of highly effective corporate Targets governance • Ensuring the independence of management and protecting the interests of minority shareholders KPIs Appropriate management and supervision of Group companies • Addressing the revised Corporate Governance Code appropriately Implementing evaluation of the effectiveness of the Board of Directors and working on priority issues based on the results of evaluation Conducting appropriate transactions between Group companies with consideration to protecting the interests of minority shareholders

(FY) 2008-2012 2013 2014 2015 2016 2017-2019 2020 2021 **Outside Directors** 1 (8) 2 (8) 3 (8) **Outside Audit & Supervisory** 3 (5) Board Members (number of Audit & Supervisory Board Members) Company with an Audit & Supervisory Board Nomination and Compensation Committee Supervisory function Supervisory Committee for Conflict of Interests in Transactions between Group Companies Evaluation of effectiveness of Board of Directors Effectiveness Regular meetings of Outside Directors and Outside Audit & Supervisory Board Members Declaration of Conduct **Compliance Standards** Policy Basic Policy on Corporate Governance DSP Group Risk Management Policy Human Resource DSP Academy, a selective training program that includes the Management Course to foster future managers, established Development

### **Executive remuneration**

The Company has the Nomination and Compensation Committee 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 remuneration for Directors. As a system of remuneration for Directors, the Company has provided as described below the policy for determining remuneration and the like for individual Directors, and the policy was determined by the Board of Directors based on the recommendation from the Nomination and Compensation Committee after the Board of Directors sought such recommendation and the Nomination and Compensation Committee deliberated the relevant matters.

### 1) System of remuneration and the like

Remuneration for the Directors (excluding Outside Directors) consists of base remuneration and performance-linked remuneration (bonuses), and this system is established 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 remuneration 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 remuneration (bonuses) is calculated by the method described in 2) below, and the ratio of such remuneration is approximately 10% of the total of remuneration and the like.

Remuneration for the Outside Directors consists of base remuneration and non-performance-linked remuneration (bonuses), and the Company adopts a remuneration 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.

The base amounts are set with respect to the base remuneration, performance-linked remuneration (bonuses) and non-performance-linked remuneration (bonuses) according to each position, such as Representative Director. The total amount of the remuneration and the like shall be not more than 700 million yen annually as approved at the Shareholders' Meeting.

### 2) Method of calculating the amount of performance-linked remuneration (bonuses)

The amount of the performance-linked remuneration (bonuses) for the Directors (excluding Outside Directors) is calculated based on the performance-linked elements and individual performance, and is calculated to be within the scope of zero to 200% of the base amount.

The performance-linked elements are evaluated by the Nomination and Compensation Committee based on the degree of achievement of targets, using the "core operating profit," which was set as a profit indicator showing

Organizational Body	Composition	Frequency of convocation	Purpose
The Board of Directors	The Directors 8 members, (including 3 Outside Directors)	Once a month as a rule	Resolving and reporting important management matters Met 21 times in fiscal 2020
The Audit & Supervisory Board	The Audit & Supervisory Board 5 members, (including 3 Outside Audit & Supervisory Board members)	Once a month as a rule	Discussing and resolving important audit-related matters Met 13 times in fiscal 2020
Nomination and Compensation Committee	The Directors 4 members, (includes 3 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 10 times in fiscal 2020
Supervisory Committee for Conflict of Interests in Transactions between Group Companies	The Directors 3 members, (consists of 3 Independent Outside Directors only)	Meets as Necessary	Deliberating on material transactions, etc. with the parent company Group from the perspective of protecting the interests of minority shareholders Met 2 times in fiscal 2020
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 28 times in fiscal 2020
Executive Committee	Executives, including the members of the Board of Directors, the Audit & Supervisory Board, and Executive Officers 25 members (including 3 Outside Directors and 3 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 2020

#### Status of convocation of the meeting of the Board of Directors (FY2020)

# **Corporate Governance**

recurring profitability of a company within the Group and serves as an original performance management indicator. The individual performance is evaluated by the Nomination and Compensation Committee based on the degree of achievement of performance targets of each Director (excluding Outside Directors). The "core operating profit" forecast publicized in the announcement of the consolidated financial results for fiscal 2019 (33 billion yen) was used as a target, and the result of fiscal 2020 was 69.6 billion yen.

### 3) Method of determining remuneration and the like

Remuneration and the like for individual Directors 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. When the Board of Directors determines to delegate the decision-making thereof to the Representative Director and President, the Representative Director and President shall determine the same, respecting the recommendation made by the Nomination and Compensation Committee to the Board of Directors.

Upon the delegation by the Board of Directors, Representative Director and President, who oversees business operations as a whole and has a good understanding of the state of the execution of duties by all Directors (excluding Outside Directors), determined the said remuneration and the like for FY2020, and the Nomination and Compensation Committee confirmed that the said remuneration and the like was in accordance with the system of remuneration for Directors. Accordingly, the Board of Directors has determined that the decision of the said remuneration and the like was in accordance with the said remuneration and the like was in accordance with the said remuneration and the like was in accordance with the

### Amount of executive remuneration (FY2020)

		Total Amount of	Amount of Remuneration by type (Millions of Yen)			
Category of Officer	Number	Remuneration (Millions of yen)	Base remuneration	Performance-linked remuneration (bonuses)	Non-performance- linked remuneration (bonuses)	
Directors (excluding Outside Directors)	6	352	304	48	-	
Audit & Supervisory Board Members (excluding Outside Audit & Supervisory Board Members)	2	51	51	_	_	
Outside Directors and Outside Audit & Supervisory Board Members	6	75	72	_	3	

(Note) 1. The respective amounts of remuneration and the like for Directors and Audit & Supervisory Board Members that were determined in the 185th Annual Shareholders' Meeting held on June 29, 2005, do not exceed 400 million yen annually for Directors, and 100 million yen annually for Audit & Supervisory Board Members. The amount of remuneration for the Directors was revised to officers concerned under this resolution were ten (10) Directors and four (4) Audit & Supervisory Board Members. The amount of remuneration for the Directors was revised to no more than 700 million yen annually by resolution of the 201st Annual Shareholders' Meeting held on June 24, 2021.

2. The total amount of remuneration for nine (9) Directors is 391 million yen, and the total amount of remuneration for five (5) Audit & Supervisory Board Members is 87 million yen.

3. The total amount of remuneration for nine Directors includes the amount of 50 million yen, which represents the bonuses paid to Directors with respect to fiscal 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
	Member, Board of Directors, Chairman Masayo Tada	•		•		•			
	Representative Director, President and CEO Hiroshi Nomura	•	•	•	•	•	•		
Directors	Representative Director, Executive Vice President Hitoshi Odagiri		•	•		•			
	Representative Director, Executive Vice President Toru Kimura	•					•	•	
	Member, Board of Directors, Senior Executive Officer Yoshiharu Ikeda	•					•	•	•
Audit & Supervisory	Yoshinori Oh-e					•	•		•
Board Members	Takashi Kutsunai		●	•		•			

(Note) 
indicates current positions and responsibilities held for at least the past two years

The Company plans to disclose the skill matrix and other disclosures required under the revised Corporate Governance Code by December 30, 2021.

# The principal activities of the Outside Directors and Outside Audit & Supervisory Board Members (FY2020)

Category	Name	Name Principal Activities	Attendance/Frequency of Convocation (Attendance Rate)
	Yutaka Atomi	He attended all twenty-one (21) meetings held by the Board of Directors during the fiscal year under review, and made statements at those meetings, primarily from the professional standpoint of a medical doctor. He attended all ten (10) meetings held by the Nomination and Compensation Committee during the fiscal year under review, and made statements at those meetings from an independent and objective standpoint. He also attended all two (2) meetings held by the Supervisory Committee for Conflict of Interests in Transactions between Group Companies during the fiscal year under review, and made statements at those meetings from the standpoint of protecting the interests of minority shareholders.	The Board of Directors: 21 times/21 times (100%) Nomination and Compensation Committee: 10 times/10 times (100%) Supervisory Committee for Conflict of Interests in Transactions between Group Companies: 2 times/2 times (100%)
Outside Directors	Saeko Arai	She attended all twenty-one (21) meetings held by the Board of Directors during the fiscal year under review, and 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. She attended all ten (10) meetings held by the Nomination and Compensation Committee during the fiscal year under review, and made statements at those meetings from an independent and objective standpoint. She also attended all two (2) meetings held by the Supervisory Committee for Conflict of Interests in Transactions between Group Companies during the fiscal year under review, and made statements at those meetings from the standpoint of protecting the interests of minority shareholders.	The Board of Directors: 21 times/21 times (100%) Nomination and Compensation Committee: 10 times/10 times (100%) Supervisory Committee for Conflict of Interests in Transactions between Group Companies: 2 times/2 times (100%)
	Nobuhiro Endo	He attended all twenty-one (21) meetings held by the Board of Directors during the fiscal year under review, and made statements at those meetings, primarily based on his extensive experience and broad perspective as a corporate executive. Among the ten (10) meetings held by the Nomination and Compensation Committee during the fiscal year under review, he attended nine (9) meetings, and made statements at those meetings from an independent and objective standpoint. He also attended all two (2) meetings held by the Supervisory Committee for Conflict of Interests in Transactions between Group Companies during the fiscal year under review, and made statements at those meetings from the standpoint of protecting the interests of minority shareholders.	The Board of Directors: 21 times/21 times (100%) Nomination and Compensation Committee: 9 times/10 times (90%) Supervisory Committee for Conflict of Interests in Transactions between Group Companies: 2 times/2 times (100%)
	Kazuto Nishikawa	He attended all twenty-one (21) 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 expert in the fields of finance and accounting.	The Board of Directors: 21 times/21 times (100%) Audit & Supervisory Board Members: 13 times/13 times (100%)
Outside Audit & Supervisory Board Members	Junsuke Fujii	He attended twenty (20) meetings out of the twenty-one (21) 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 based on his extensive experience and broad perspective as a corporate executive.	The Board of Directors: 20 times/21 times (95%) Audit & Supervisory Board Members: 13 times/13 times (100%)
	Yoshio Iteya	He attended all twenty-one (21) 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.	The Board of Directors: 21 times/21 times (100%) Audit & Supervisory Board Members: 13 times/13 times (100%)

### 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
	Yutaka Atomi	Yutaka Atomi has extensive experience and expertise as a medical doctor. He has been appointed as an Outside Director in the expectation that he will be able to contribute to the management for the sustained growth of the Group and increase of its corporate value using his experience and expertise, while supervising the management from an independent and objective standpoint as an Outside Director.	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 expectation that she will be able to contribute to the management for the sustained growth of the Group and increase of its corporate value using her experience and expertise, while supervising the management from an independent and objective standpoint as an Outside Director.	Accounting and management
Outside Directors 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 expectation that he will be able to contribute to the management for the sustained growth of the Group and increase of its corporate value using his knowledge and experience, while supervising the management from an independent and objective standpoint as an Outside Director.	Management
	Minoru Usui	Minoru Usui 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 providing products including information-related equipment and related services at a global level. He has been appointed as an Outside Director in the expectation that he will be able to contribute to the management for the sustained growth of the Group and increase of its corporate value using his knowledge and experience, while supervising the management from an independent and objective standpoint as an Outside Director.	Management
Outside Audit &	Junsuke Fujii	Junsuke Fujii 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 major commercial bank and a company providing consulting and other related services. He has been appointed as an Outside Audit & Supervisory Board Member in the expectation that he will be able to contribute to the auditing of the Group using his knowledge and experience.	Management
Supervisory Board Members 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 expectation that he will be able to contribute to the auditing of the Company using his expertise and experience.	Laws
	Mayumi Mochizuki	Mayumi Mochizuki has extensive experience and expertise as a pharmacologist. She has been appointed as an Outside Audit & Supervisory Board Member in the expectation that she will be able to contribute to the auditing of the Group using her experience and expertise.	Pharmacy

### **Corporate Governance**

### **Messages from Outside Directors**



Yutaka Atomi

I supervise and give advice at Board of Directors meeting mainly from the perspective of my experience as a medical doctor and university president. At Sumitomo Dainippon Pharma, the diverse members of the Board of Directors give their opinions in a free and open manner based on their own experience and backgrounds. Moreover, I believe we have been able to have particularly robust discussions for important projects as a result of extremely thorough preliminary explanations from the secretariat.

We recognize there are significant expectations on Outside Directors for supervision to ensure the interests of minority shareholders are not infringed. The Supervisory Committee for Conflict of Interests in Transactions between Group Companies, which was established in April 2020 and made up entirely of Independent Outside Directors, undertakes this role. This committee discusses primarily the appropriateness of the purpose and prices of important transactions with our parent company or its subsidiaries. Further, the committee confirms there are no issues from the perspective of protecting the interests of minority shareholders, and the Board of Directors makes the final decision in this process. In fiscal 2020, the establishment of S-RACMO Co., Ltd., a joint venture company between us and our parent company, was discussed in this manner and it was confirmed there were no issues.

Considering the state of the world, the Sustainable Development Goals advocated by the United Nations are significant issues for corporations. While the core business of pharmaceutical companies benefits peoples' health and wellbeing, we need to be more proactive than simply promoting our core business activities. I believe the Company's management clearly understand this situation and is setting and executing appropriate goals.



Saeko Arai

I supervise and give advice at Board of Directors meetings from a different perspective, based on my expertise and experience to enhance corporate value in the medium to long term, from the viewpoint of minority shareholders, investors and patients. The Board of Directors is managed appropriately by the Chairman and is a forum conducive to robust discussions so that vigorous discussions between inside and outside Directors and Audit & Supervisory Board Members are held. The membership of the Board of Directors has achieved a certain level of diversity, and there are ongoing efforts to ensure diversity. I also have expectations for its ongoing focus on human resource development.

Furthermore, there are increasing opportunities to discuss business plans and priority management issues, even outside the Board of Directors meetings. The effectiveness of the board is steadily increasing through an ongoing cycle of annual effectiveness evaluations of the Board of Directors, that is, discussions of the results, establishment of targets, and the process of making improvements.

The Company has to date undertaken proactive dialogues, at the opportunities such as ESG meetings, to exchange opinions with its shareholders. Moreover, there are expectations for this to be further enhanced, and I believe initiatives to this end should be progressed.

In an environment where rapid responses to changes of the times are required, I believe it is desirable to link executive compensation where necessary to appropriate KPIs for corporate material issues. In addition, environmental disclosure requirements are being strengthened, and there is increasing importance to meet these requirements not only within our Group, but also throughout our supply chain. We are undertaking measures to meet these requirements.



Nobuhiro Endo

I supervise and give advice to strengthen governance for management of the Company from the perspective of whether there are risks in what we consider common sense at the Company.

The Company is devising ways for sharing detailed information with Outside Directors by providing opportunities for explanations of agenda items in advance of Board of Director meetings, in addition to committee for sharing the management situation with all Directors, Audit & Supervisory Board Members, and Executive Officers. This is making the discussions more vigorous. Proactive opinions from the diverse Outside Directors and the Outside Audit & Supervisory Board Members is invigorating the discussions, and the discussions have been of a high quality.

Because the Company undertakes advanced technological research, I believe geopolitical perspectives are necessary, including from an economic security viewpoint. In particular, it is important to constantly be aware of risk management.

I believe that in a long term strategy it is important to take on challenges in areas of potential growth without restricting the boundaries of the strategy. Particularly the future society proposed by the Japanese government, Society 5.0, is a data-based society and we are in the process of changing from a society of individual optimums to a society of overall optimum value. It is essential we appropriately respond to these changes; therefore, we are focused on a strategy that includes collaboration with other companies.

The Company has already recognized that having both ourselves and our parent- company listed is a risk from the perspective of protecting the interests of minority shareholders. To this end, the Company has established the Supervisory Committee for Conflict of Interests in Transactions between Group Companies. While currently it is unlikely for an issue to arise, it is important to constantly be aware of this as a risk from the perspective of predicting problems in advance.



Minoru Usui

I was appointed as an Outside Director at the 2021 annual shareholders' meeting. My greatest strengths are understanding the potential inherent in technology and knowledge and expertise related to commercializing these technologies based on my experience creating global businesses by nurturing areas of potential uncovered through research and development. At Sumitomo Dainippon Pharma, the R&D divisions play an extremely significant role. I believe I can make the most of the Company's strengths in this area through proposals such as for refining and defining ways of implementing its strategic focus, developing human resources, and for improving its organizational culture.

My role as an Outside Director is to maximize the Group's capacity for creating new value by utilizing my experience after first understanding the reason for existence and the ideal status of the Group based on its strengths.

To solve social issues, we must act swiftly from long term and overarching and broad perspectives. We can appropriately respond to opportunities to expand our business and to risks that may cause our business to decline by learning from changes to our operating environment and evolving as an organization. It is important to foster a corporate culture where we all work in such a manner, and it is extremely important we have the leaders to foster and drive this culture.

Further, I believe improving the quality of dialogue with shareholders will help protect the interests of minority shareholders, and I will give advice and supervision in line with this way of thinking and will work to enhance corporate value.

### **Corporate Governance**

#### **Messages from Outside Audit & Supervisory Board Members**



Junsuke Fujii

I get a strong sense of the zeal of executive managers and division leaders for organizational management, a clear sense of their ideas and concrete policies, and the pride and passion employees have for their work, when listening to internal division meetings, reporting sessions, presentations, and so on. I believe, from my many years of experience in personnel-related work, that this kind of motivation of personnel is extremely important in realizing our globalized and diversified business strategy.

When auditing, I have access to a wide range of information from full-time Audit & Supervisory Board Members and have ample opportunities for questions and answers. Through its collaboration with Internal Auditing Department, the Audit & Supervisory Board has forums for receiving reports on audit results and exchanging opinions, and accurately points out risks and issues, and works to make improvements. Moreover, we cooperate substantially with the Accounting Auditor.

The presence and importance of overseas subsidiaries is growing, and the Group is proceeding with clarifying the roles of overseas subsidiaries in an already global R&D system. Moreover, the Group has also established as a system a forum for domestic and overseas employees to have discussions. I hope that as information sharing progresses and transparency increases, such integration will progress further, and the Group will achieve innovative drug discovery through employees' friendly competition.



**Yoshio Iteya** 

As a lawyer, I endeavor to objectively judge the legality of business execution by Directors. Also, as a lawyer specializing in international affairs, I try to focus on the overseas expansion and globalization of the Group's business.

Regarding discussions and effectiveness of the Board of Directors, there is active and comprehensive discussions on a wide range of themes, and I believe governance is effective. As for cooperation with Internal Auditing Department, we have established forums where Outside Audit & Supervisory Board Members can directly exchange opinions with the internal auditors, enabling us to understand the details of the business; and this support and response has been highly appreciated.

Regarding responses to the environmental changes of COVID-19, the Company rapidly implemented measures for remote Board of Directors and Audit & Supervisory Board meetings to enable participation in discussions using tools such as telephone conferencing and iPads.



I was appointed as an Outside Audit & Supervisory Board Member at the 2021 annual shareholders' meeting. I have worked for pharmaceutical companies, hospitals, and universities. From my experience, I have a deep understanding of the way a pharmaceutical company should be to ensure it is trusted from the perspective of healthcare professionals and patients. In addition, through my involvement with the Pharmaceutical Affairs and Food Sanitation Council and the Japanese Society of Drug Informatics, I consider what medical information is necessary for appropriate drug therapy, and would like to be able to give advice that makes the best use of my expertise, on what information should be created by pharmaceutical companies.

I believe, based on the Company's track record of transforming METGLUCO<sup>®</sup> into a new product, Sumitomo Dainippon Pharma is a company of integrity that persistently provides thorough information on risk factors.

I would like to contribute to the management of the Company through my auditing work by making the most of my experience as a healthcare professional.

## 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 2020, 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 2020, the Company conducted a questionnaire on all the Directors and Audit & Supervisory Board Members during the period from February 2021 to March 2021. 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 May 2021.

### 2) Survey Categories

The major topics of the questionnaire for fiscal 2020 were as follows (topic 13 was 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
- 13) Method of holding the meeting of the Board of Directors

### 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 2020 and those in the past), all the Directors and Audit & Supervisory Board Members exchanged opinions at the meeting of the Board of Directors in May 2021. 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 2020 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 2019.

### 4) Major matters to be addressed in fiscal 2021

The following agendas have been identified as major matters to be addressed in fiscal 2021 as a result of the evaluation of the effectiveness of the Board of Directors for fiscal 2020.

- Further enhancement of discussions for risk management
- Provision of the appropriate number of agenda items and appropriate time for deliberation
- Enhancement of training.

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, 2021) 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

# **Corporate Governance**

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, in September 2020, the Company and Sumitomo Chemical established and began operating S-RACMO Co., Ltd., a joint venture engaged in the CDMO business to develop manufacturing methods and manufacture products in the regenerative medicine/cell therapy field.

#### 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. With regard to decision-making on important matters at subsidiaries, including subsidiaries in the U.S., we require clarification of the functions of the Board of Directors and other decision-making bodies at those subsidiaries. We also require them to consult with us in advance and report after the fact in a timely and appropriate manner taking into consideration the impact on the entire Group to enhance Group-wide governance. Going forward, we will continue to strengthen group governance, aiming for sustained growth as a united group. We also strive to consider protection of the interest of minority shareholders of listed subsidiaries.

### Strategic shareholdings

Sumitomo Dainippon Pharma shall not hold any shares of other companies except when such shareholding supports the sustained 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 26 as of May 31, 2021.

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.

Upon implementing the strategic alliance with Roivant, the Company acquired its shares (unlisted) in December 2019. The ratio of such shares to total equity on the Group's Consolidated Statement of Financial Position as of March 31, 2021 was 19.0%.

### 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, "Smart Voting" 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, the presentation by the President and the summary of question-and-answer session at the annual shareholders' meeting are also posted on our website.

### 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

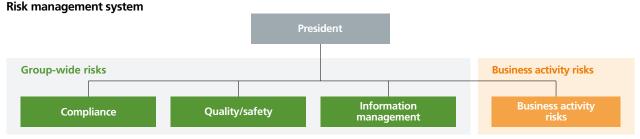
### **Risk management**

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

### Rebuilding business continuity plans (BCP)

Sumitomo Dainippon Pharma formulates its business continuity plans (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, a new



➡ Please see pages 26 and 169 for Quality/safety of risk management.

# **Corporate Governance**

infectious disease (pandemic), etc.

However, in recent years there have been many natural disasters other than earthquakes, such as typhoons and local heavy rain. Given these circumstances, we are rebuilding our BCP to be effective for responding to diverse disasters and unexpected situations, while also establishing sustainable BCP management (BCM). Our goal is to strengthen the Company's risk management, transition to a more effective BCP, and move forward in establishing a more effective management cycle.

### Initial response plan

We separated certain functions, such as the information gathering functions and publicity functions, that had previously been handled by Disaster Response Headquarters, and launched a Crisis Management Team (CMT)\* that, immediately after a disaster occurs, starts gathering information, outlines the status of damage, offers advice on whether a Disaster Management Headquarters should be established, and if established, works to gather further information.

We carry out regular, remote CMT training and other measures with the objective of increasing our swift and precise first-response capabilities. Going forward, we will carry out training to facilitate coordination between the CMT and administrative offices (the Disaster Management Headquarters in the disaster area) as well as the Disaster Response Headquarters, and will work to boost crisis management capabilities during times of disaster.

\* CMT (Crisis Management Team): A team that is quickly assembled after a disaster breaks out, then starts gathering information, surveying the status of damage, and offering advice on whether a Disaster Response Headquarters should be established. If a Disaster Response Headquarters is established, the CMT continues gathering information, outlining the situation, and conducting similar tasks.

### 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 Information Technology security, etc. to minimize risks.

# Management of confidential information and inside 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. Additionally, we regularly hold training for officers and employees and we work to increase their level of awareness.

### 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.



### 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 2020, CSIRT conducted response training based on a cyberattack scenario.

### Material issues Risk management

- Targets Implementing risk assessment and taking countermeasures
  - Rebuilding of business continuity plans (BCP)
  - Proper information management (management of confidential information, internal information and personal information, Information Technology security)
- KPIs Implementing risk assessment and examining and implementing appropriate countermeasures based on results of assessment
  - Rebuilding, and implementing training and drills of business continuity management (BCM) and business continuity plans (BCPs)
  - Provision of education and training aimed at proper information management
  - Number of serious information leaks and other incidents

### 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 2020, each compliance committee held meetings remotely 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.

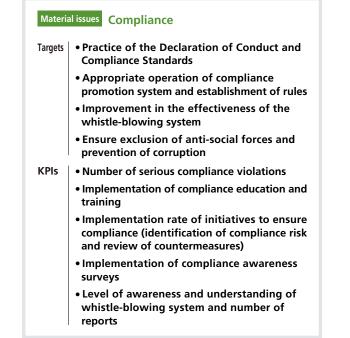
The Company rejects any relationships whatsoever with anti-social forces and, when signing business-related contracts, performs adequate due diligence on the contracting parties and their characteristics. Special provisions have been stipulated allowing for the termination of a contract signed with a counter party that the Company



### Framework for compliance implementation

### **Corporate Governance**

deems to be an anti-social force. Additionally, from the perspective of preventing corruption in business activities, the Company has stipulated Corruption Prevention Guidelines, while also specifying provisions against corruption in new transaction contracts that accompany the acceptance of compensation.



### Fair and transparent corporate activities

### Promoting communication with stakeholders

In its Declaration of Conduct, Sumitomo Dainippon Pharma has stated its commitment to "7. Build harmonious relationships with society," and is working to foster a high level of awareness as a corporate citizen.

We place importance on stakeholder engagement based on dialogue (stakeholder dialogue) with all of the stakeholders involved in the Company, including patients and their families, healthcare professionals, local communities, collaboration partners, employees, shareholders and investors, and business partners. We are working to solve social issues by proactively identifying what stakeholders expect and demand of us and reflecting these in our business and social contribution activities. → Please see page 23 for relationships with stakeholders.

# Communication with patients and healthcare professionals

Sumitomo Dainippon Pharma has established a Product Information Center 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. In FY2020, the Product Information Center engaged in approximately 3,800 inquiries from patients and their families, and approximately 34,800 inquiries from healthcare professionals.

Sumitomo Dainippon Pharma complies with relevant laws and regulations, the Ministry of Health, Labour and Welfare's Guidelines for Provision of Sales Information on Prescription Drugs, the Fair Competition Code, the Japan Pharmaceutical Manufacturers Association (JPMA) Code of Practice, the IFPMA Code of Practice, internal rules, etc. and engages in fair and transparent activities when collaborating with healthcare professionals and patient group. We also disclose information on cash payments and the like to healthcare professionals and patient group in accordance with the JPMA Transparency Guideline for the Relation between Corporate Activities and Medical Institutions and the JPMA Transparency Guideline for the Relation between Corporate Activities and Patients' Groups.

#### **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 December 2020, Sumitomo Dainippon Pharma held the third ESG meeting. In March 2021, we held a meeting on the business of Sumitovant, a subsidiary of the Company.

We conduct regular visits for foreign shareholders, but these meetings were held online in fiscal 2020 due to the impact of COVID-19. 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 hold meetings for individual investors a number of times each year (seven meetings in fiscal 2019). However, in fiscal 2020, we held one online meeting due to the impact

### of COVID-19.

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 and audio streaming and transcripts),

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.

# Material issues Fair and transparent corporate activities

- Targets Sincere corporate activities contributing to the enhancement of stakeholder engagement
- KPIs Number of stakeholder dialogues
  - Ensuring transparency on relationships with healthcare professionals and patient groups
  - Promotion of appropriate provision of information based on scientific evidence

## **Respecting human rights**

Sumitomo Dainippon Pharma respects the human rights of all stakeholders involved with the Company. In the "Declaration of Conduct: Item 5. Respect Human Rights," we clearly support the Universal Declaration of Human Rights and Core Labour Standards. And in the "Compliance Standard: Item 25. Prohibition of Harassment including Discrimination" clearly rejects any discrimination or harassment based on race, nationality, ethnicity, gender, age, religion, faith, belief, sexual orientation, gender identity (LGBTQ), academic background, disability, disease and the like.

Sexual harassment and power harassment in the workplace should be addressed as important issues that can relate to the violation of human rights. To prevent any harassment, Sumitomo Dainippon Pharma Office Regulations clearly stipulates anti-harassment policies including standards of disciplinary action.

Going forward, we will establish the Basic Human Rights Policy as our global policy in order to further promote our past initiatives to establish an appropriate working environment and respect the human rights of our business partners, including suppliers in the supply chain, and all of our stakeholders.

### Material issues Respecting human rights

- Targets 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
- KPIs Formulation of a basic policy for human rights
  - Promotion of understanding of and action on the basic policy at Group companies
  - Encouragement of respect for human rights by business partners, including suppliers

**Board Members and Executive Officers** 

# **Directors / Audit & Supervisory Board Members**



### Directors

#### Masayo Tada Member, Board of Directors, Chairman

- 1968: Joined Sumitomo Chemical Co., Ltd.
  1968: Joined Sumitomo Chemical Co., Ltd.
  2005: Joined the former Sumitomo Pharmaceuticals Co., Ltd., Managing Executive Officer
  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
  2012: Director, Chairman of the Company (to the present)

#### 2 Hiroshi Nomura **Representative Director, President and Chief Executive Officer**

- 1981: Joined Sumitomo Chemical Co., Ltd. 2004: Senior Director of Finance & Accounting Department of the former Sumitomo Pharmaceuticals Co., Ltd.
   2007: Senior Director of Global Corporate Strategy
   2008: Iojand the Company

- 2007: Senior Director of Global Corporate Strategy
  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
  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)

### Hitoshi Odagiri Representative Director,

**Executive Vice President** 

# Sales & Marketing Division Executive Director, Sales & Marketing Division Senior Director, CNS Sales Department Head of Japan Business Unit

- Head of Japan Business Unit
  1979: Joined Inabata & Co., Ltd.
  1984: Joined the former Sumitomo Pharmaceuticals Co., Ltd.
  2004: Senior Director of Marketing Administration
  2005: Senior Director of Strategic Marketing & Planning
  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 Gales & Marketing Division
  2016: Senior of the Board of Directors and Senior Executive Officer of the Board of Directors and Senior Executive Officer of the Company
  2017: Representative Director and Executive Vice President of the Company
  2021: Representative Director and Executive Vice President of the Company
  2021: Representative Director and Executive Vice Company (to the present)

# 4 Toru Kimura

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

**Chief Scientific Officer** Regenerative & Cellular Medicine Office; Regenerative & Cellular Medicine Kobe Center; **Regenerative & Cellular Medicine Manufacturing** 

- Plant
- 1989: Joined Sumitomo Chemical Co., Ltd. 1992: Joined the former Sumitomo Pharmaceuticals Co., Ltd. 2009: Senior Director of Genomic Science Laboratories of the
- Company 2010: Senior Director of Research Planning & Management of the

- 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 Directors and Senior Executive Officer of the Goard of Directors and Senior Executive Officer of the Company
  2020: Chief Scientific Officer of the Company (to the present)
  2021: Representative Director and Executive Vice President of the Company (to the present)

# Yoshiharu Ikeda

Member, Board of Directors, Senior Executive Officer

Regulatory Affairs; Medical Information; Medical Affairs; Corporate Regulatory Compliance & Quality Assurance Division; Technology Research & Development Division; Manufacturing Division Executive Director, Corporate Regulatory Compliance & Quality Assurance Division Deputy Head of Japan Business Unit

- 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 Director of the Technology Research & Development Division 2016: Senior Executive Officer, Executive Director of the
- Manufacturing Division 2020: Member of the Board of Directors, Senior Executive Officer
- and Executive Director of Corporate Regulatory Compliance & Quality Assurance Division of the Company (to the present)

9 Yutaka Atomi

- Member, Board of Directors (Outside)

- Intern Dector 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
  2004: Dean of the School of Medicine of Kyorin University
  2013: Outside Audit & Supervisory Board Member of the Company (to the present)
  2018: President of the Panceras Research Foundation of Japan
  2019: Outside Audit & Supervisory Board Member of Japan
  2019: Outside Audit & Supervisory Board Member of Sanki Engineering Co., Ltd. (to the present)



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

- 1987: Joined Eiwa Audit Corporation (currently, KPMG AZSA LLC) 2002: Established Grata, 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
- 2017: Outpute Audit of Supervisory Board Member of AEON Credit service Co., Ltd. (to the present)
  2018: Outpute Audit & Supervisory Board Member of AEON Credit Service Co., Ltd. (to the present)
  2018: Outpute Member of the Board of Directors of the Company (to the present)
  2018: Outpute 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)

### Nobuhiro Endo Member, Board of Directors (Outside)

- 1981: Joined NEC Corporation 2006: Senior Vice President and Executive General Manager of the Mobile Network Operations Junit 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
- 2016: Chairman of the Bodru (hepresentative bircetory of the 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 corporation

- the present) 2019: Director and Chairman of the Board of NEC Corporation (to the
- 2019: Outside director of Tokio Marine Holdings, Inc. (to the present)

### Minoru Usui

- Member, Board of Directors (Outside)
- 1979: Joined Shinshu Seiki Co., Ltd. (currently, Seiko Epson

- 1979: Joined Shinshu Seiki Co., Ltd. (currently, Seiko Epson Corporation)
  2002: Director of Seiko Epson Corporation
  2005: General Administrative Manager of the Production Engineering & Development Division of Seiko Epson Corporation
  2007: General Administrative Manager of the Corporate Research & Development Division of Seiko Epson Corporation
  2007: Managing Director of Seiko Epson Corporation
  2007: Managing Director of Seiko Epson Corporation
  2008: President and Representative Director of Seiko Epson Corporation
  2009: Chairman and Director of Seiko Epson Corporation (2002: Chairman and Director of Seiko Epson Corporation (16 the present)
- present) 2021: Outside Member of the Board of Directors of the Company (to
- the present) 2021: Outside Director of IHI Corporation (to the present)

#### Audit & Supervisory Board Members

### Yoshinori Oh-e 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 of Business Development
- 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)

# 🔟 Takashi Kutsunai

### Audit & Supervisory Board Member

- 1981: Joined Sumitomo Chemical Co., Ltd. 1984: Joined the former Sumitomo Pharmaceuticals Co., Ltd. 2004: Senior Director of General Affairs & Human Resources 2005: Senior Director of Human Resources of the Company
- 2005: Senior Director of Human Resources 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)

### 12 Junsuke Fujii

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

- Soined Sumitomo Bank (currently, Sumitomo Mitsui Banking Corporation)
   Director and Senior Managing Executive Officer of Sumitomo Mitsui Banking Corporation
   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) 2017: Special Adviser, The Japan Research Institute, Limited (to
- 2007: Special Advise, the Japan Research institute, Linited (to the present) 2020: Outside Audit & Supervisory Board Member of House Foods Group Inc. (to the present)

### Yoshio Iteya

Audit & Supervisory Board Member (Outside)

- 1983: Admitted to the Bar (Japan)
  1989: Admitted to the Bar (New York)
  1992: Partner at Mori Hamada & Matsumoto
  2000: Lecturer at the Graduate School of International Corporate Strategy of Hitotsubashi University (currenty, 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)
- Company (to the present) 2021: Partner at Anderson Mori & Tomotsune (to the present)

#### 14 Mayumi Mochizuki Audit & Supervisory Board Member (Outside)

- 1976: Joined Nippon Roche K.K. (currently, Chugai Pharmaceutical Co., Ltd.)
- 1983: Joined the Department of Pharmacy of Kitasato University

- 1983: Joined the Department of Pharmacy of Kitasato University Hospital
  2007: Professor at Kyoritsu University of Pharmacy (currently, the Faculty of Pharmacy of Keio University)
  2009: Associate Dean in Pharmacy at the Graduate School of Pharmaceutical Sciences of Keio University
  2013: Dean of the Faculty of Pharmacy and Dean of the Graduate School of Pharmaceutical Sciences of Keio University
  2015: Director of the Department of Pharmacy at Keio University
  2019: Adviser of the International Medical Information Center (to the present)
  2020: Special Adviser of the International University of Health and Welfare (to the present)
- the presence 2020: Special Adviser of the International Otherson, Welfare (to the present) 2020: Vice President of Science Council of Japan (to the present) 2021: Outside Audit & Supervisory Board Member of the Company (to the present)

**Board Members and Executive Officers** 

# **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 of Global Business Development and Head of Global Business Development
- 2017: Executive Officer, Senior Director of Global Corporate Strategy 2019: Senior Executive Officer (to the present)



Senior Executive Officer Global Corporate Strategy; Global Business

- 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
  2014: Deputy Executive Director of Drug Research Division and Senior Director of Global Business Development Office
  2017: Executive Officer
  2020: Senior Executive Officer (to the present)



### Hideyuki Harada **Senior Executive Officer**

**Drug Research Division** Senior 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 Officer, 2017: Executive Officer, Executive Officer, Senior Executive Officer, Carlo Senior Executive Research Director of Drug Research Division (for the oresent)

- (to the present)



### Atsuko Higuchi Executive Officer Corporate Governance; Corporate

**Communications; Human Resources** 1986: Joined Sumitomo Chemical Co., Ltd.

1992: Joined Shined Chemicano Chemicano Pharmaceuticals 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 (to the present)



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

1982: Joined Sumitomo Chemical Co., Ltd.

1984: Joined the former Sumitomo Pharmaceuticals Co., Ltd. 2010: Senior Director of Higashi-Nippon Region Minami-Tohoku

- Bracch
   Serior O Ingeati-rwippor neglon Ninami-Tohoku
   Branch
   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 and
   Senior Director of Sales & Marketing Management
   2021: Executive Officer,
   Deputy Executive Director of Sales & Marketing Division (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

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

Shigeyuki Nishinaka

**Development: International Business** Management



#### Isao Shimizu **Executive Officer**

#### **Executive Research Director, Drug Research** Division

- 1991: Joined the former Dainippon Pharmaceutical Co., Ltd. 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) 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 Officer, Executive Vice President and Chief Corporate Strategy Officer, Sunovion Pharmaceuticals Inc. (to the present)



# Kenji Ueno **Executive Officer** Executive Director, Technology Research & Development Division

- 1990: Joined the former Dainippon Pharmaceutical Co., Ltd.
  2014: Senior Director of Ibaraki Plant
  2016: Senior Director of Manufacturing Management and Senior Director of Pocurement
  2019: Deputy Executive Director of Manufacturing Division and Senior Director of Suzuka Plant
  2020: Executive Director of Echnology Research & Development Division
  2012: Executive Officer, Executive Officer, Executive Officer, Division (to the present)



#### Antony Loebel **Executive Officer**

### President and CEO, Sunovion Pharmaceuticals Inc.

- 2001: Joined Pfizer Inc.
  2007: Joined Dainippon 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 Dainippon Pharma Oncology, Inc. Global Head of Oncology

1991: Joined Pfizer Inc.

- 1991: Joined Přízer Inc.
  2008: Joined Incyte Corporation
  2013: Joined Boston Biomedical Pharma, Inc. (currently, Sumitomo Dainippon Pharma Oncology, Inc.)
  2017: Executive Officer,
  CEO, Boston Pharma Oncology, Inc.)
  2020: Executive Officer,
  CEO, Sumitomo Dainippon 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	2012	2013	2014	2015	2016	2017	
RESULTS OF OPERATIONS:							
Net sales	¥350,396	¥347,724	¥387,693	¥371,371	¥403,206	¥411,639	
Overseas sales revenue	130,243	133,125	174,286	174,911	215,055	227,495	
Ratio to net sales	37.2%	38.3%	45.0%	47.1%	53.3%	55.3%	
Cost of sales	98,857	101,686	104,100	101,228	104,471	100,071	
Selling, general and administrative expenses	231,137	220,994	241,450	246,868	261,805	259,066	
(Research and development costs)	56,891	59,844	69,804	71,304	82,034	80,819	
(Ratio to net sales)	16.2%	17.2%	18.0%	19.2%	20.3%	19.6%	
Operating income	20,402	25,044	42,143	23,275	36,930	52,501	
Operating margin	5.8%	7.2%	10.9%	6.3%	9.2%	12.8%	
Net income attributable to owners of the parent	8,630	10,044	20,061	15,448	24,697	28,733	
FINANCIAL POSITION:							
Total assets	¥559,410	¥607,219	¥659,033	¥711,584	¥707,717	¥783,640	
Net assets	319,227	349,248	398,540	451,021	446,473	460,389	
OTHER STATISTICS:							
Capital expenditures	¥ 8,742	¥ 12,384	¥ 23,421	¥ 10,676	¥ 9,785	¥ 10,619	
Depreciation and amortization	40,232	35,085	26,777	19,226	20,267	18,649	
PER SHARE OF COMMON STOCK:							
Basic net income	¥ 21.72	¥ 25.28	¥ 50.49	¥ 38.88	¥ 62.16	¥ 72.32	
Net assets	803.47	879.03	1,003.11	1,135.21	1,123.76	1,158.80	
Cash dividends applicable to the y	ear 18.00	18.00	18.00	18.00	18.00	20.00	
FINANCIAL INDICATORS:							
ROE	2.7%	3.0%	5.4%	3.6%	5.5%	6.3%	
ROA	1.5%	1.7%	3.2%	2.3%	3.5%	3.9%	
Equity ratio	57.1%	57.5%	60.5%	63.4%	63.1%	58.8%	
Dividend payout ratio	82.9%	71.2%	35.7%	46.3%	29.0%	27.7%	

(Note) 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. Because provisional accounting treatment for business combinations conducted during the fiscal year ended March 31, 2020 was fixed during the fiscal year ended March 31, 2021, the allocation of acquisition costs was reviewed. Consequently, the figures for the year ended March 31, 2020 were adjusted retroactively.
 3. To coincide with the adoption of the IFRS, the Group has set "Core operating profit" as an earnings indicator showing the Company's recurring profitability. Core operating profit is calculated by deducting from operating profit any gains and losses resulting from nonrecurring factors (hereinafter, "non-recurring items") designated by the Group. Revenue and expenses under "RESULTS OF OPERATION (IFRS)" are reported by the "Core basis" figures after adjusting for non-recurring items.

2019

¥459,267

293,325

186,143

82,891

77,299

57,884

48,627

¥834,717

498,138

498,138

¥ 13,231

¥ 122.39

1,253.82

28.00

11.8%

10.2%

5.9%

59.7%

22.9%

13,976

18.0%

16.8%

63.9% 113,109

2020

¥ 482,762

307,819

128,346

189,979

92,607

71,982

83,239

40,753

¥1,256,534

635,860

532,670

11,990

17,365

102.58

1,340.74

28.00

3.3%

7.9%

3.9%

42.4%

27.3%

¥

¥

19.2%

14.9%

63.8%

Millions of yen		
2018	IFRS	2018
	<b>RESULTS OF OPERATIONS:</b>	
¥477,966	Revenue	¥466,838
	Overseas sales revenue	281,434
290,321	Ratio to revenue	60.3%
60.7%	Cost of sales	112,345
119,852	Selling, general and administrative expenses	186,176
292,291	Research and development expenses	86,881
	Ratio of R&D expenses to revenue	18.6%
91,397	Core operating profit	90,604
19.1%	Ratio of core operating profit to revenue	19.4%
	Operating profit	88,173
65,823	Net profit attributable to owners of the parent	53,448
	FINANCIAL POSITION:	
37,525	Total assets	¥809,684
	Total equity	452,723
¥801,425	Equity attribute to owners of the parent	452,723
	OTHER STATISTICS:	
483,050	Capital expenditures	¥ 10,184
	Depreciation and amortization	12,887
¥ 10,060	PER SHARE OF COMMON STOCK:	
19,909	Basic net profit	¥ 134.53
Yen	Equity attributable to owners of the parent	1,139.50
¥ 94.45	Cash dividends applicable to the year	28.00
1,215.84	FINANCIAL INDICATORS:	
28.00	ROIC	12.1%
28.00	ROE	12.4%
	ROA	6.7%
8.0%	Ratio of equity attributable to owners of the parent to total assets	55.9%
4.7%	Dividend payout ratio	20.8%
60.3%		
29.6%		

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

Millions of yen

2021

¥ 515,952

327,286

137,490

211,770

97,082

69,583

71,224

56,219

¥1,308,127

648,178

580,570

12,660 22,673

141.50

1,461.31

28.00

3.1%

10.1%

4.4%

44.4%

19.8%

Yen

¥

¥

18.8%

13.5%

63.4%

# **Financial Policy**

# Massage from the President



### **Hiroshi Nomura**

Representative Director, President and Chief Executive Officer

### Implementing strategic investment based on the capital allocation policy in Mid-term Business Plan 2022 to acquire post-LATUDA growth drivers

In our capital allocation policy under Mid-term Business Plan 2022 ("the MTBP"), in addition to aggressive R&D investment, we set a range of ¥300 billion to ¥600 billion for strategic investment with financial leverage over the five years from fiscal 2018. Based on this policy, we invested approximately ¥330 billion on the strategic alliance with Roivant Sciences Ltd. (hereinafter, "Roivant") in fiscal 2019, and we had invested a total of approximately ¥360 billion by the end of fiscal 2020, which included the subsequent acquisition of remaining shares of Urovant Sciences Ltd. (hereinafter, "Urovant") to make it a wholly

owned subsidiary. Through these strategic investments, we have acquired multiple pipeline assets, including late-stage development assets, which are expected to become large-scale drivers of our post-LATUDA growth. In addition to this, we will continue to secure ¥90 billion or more in R&D investment until fiscal 2022. Although we have added R&D expenses for Sumitovant group compounds to the ¥450 billion initially planned under the MTBP (cumulative total for five years), we intend to invest a total of approximately ¥460 billion by reducing existing R&D expenses. We will continue striving to create innovative products and healthcare solutions.

### Reducing interest-bearing liabilities to maintain financial soundness over the medium to long term

Our policy on fund procurement is to raise funds giving due consideration to maintaining financial soundness, based on funding costs and the impact on our credit ratings. For the strategic alliance in fiscal 2019, we raised ¥270 billion through short-term borrowings in order to pay the consideration, and we refinanced ¥120 billion of that amount in September 2020 through hybrid bonds issue aimed at raising capital. We did this because we determined it was the optimal way to both increase shareholder value with an awareness of capital efficiency and strengthen our financial base from the perspective credit rating evaluations. Moreover, at the end

### Financial policy: Ensure strategic investment with financial leverage

Ensure strategic investment of ¥300 billion to ¥600 billion over five years
Approximately ¥360 billion in strategic investment implemented up to fiscal 2020



Fiscal 2018 <b>¥82.9 billion</b>	Fiscal 2019 <b>¥92.6 billion</b>	Fiscal 2020 <b>¥97.1 billion</b>	Fiscal 2021 <b>¥95 billion</b> (forecast)	
-------------------------------------	-------------------------------------	-------------------------------------	---	--

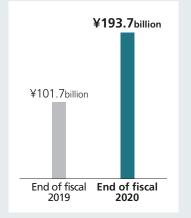
of 2020, we also refinanced ¥125 billion of the ¥150 billion balance through long-term borrowings from financial institutions for the purpose of stabilizing our financial position. We believe we have maintained a high level of financial soundness in terms of cash flow.

Our policy is to reduce the Group's interest-bearing liabilities of ¥273.8 billion (as of March 31, 2021) in order to maintain financial soundness over the medium to long term. We plan to repay a total of approximately ¥25 billion in interest-bearing liabilities using our own funds in fiscal 2021 and fiscal 2022. Thereafter, we will continue to repay long-term borrowings and redeem bonds to improve our net cash position.

### Pursuing management efficiency to maintain R&D investment through structural reform aimed at strengthening business structure

Currently, we are not considering any more large-scale investments,

# Cash and cash equivalents at end of year



such as M&As, during the current MTBP. However, we do plan to continue investing to acquire development pipeline assets. We believe we will greatly increase the flexibility of our investment strategy by reducing interest-bearing liabilities and strengthening our financial position. To this end, we are promoting structural reform to enhance company strength in anticipation of LATUDA® LOE (Loss of Exclusivity) in the U.S. and future changes in the environment. We are working to maximize profits and reduce costs through external alliances, review the allocation of investment to the R&D pipeline, and optimize selling, general and administrative expenses to match business scale. We will also improve cash flows through sale of assets with LOE and shares owned, and create cost synergies by strengthening collaboration between Group companies.

At the same time, aiming for medium- to long-term growth, we will focus efforts on the early expansion of Sumitovant group's products, and plan to continue with at least ¥90 billion in annual R&D investment until fiscal 2022. By bolstering the management base and business structure in this way, we aim to achieve sustained growth by increasing management efficiency and investing in growth on a global basis.

### Promoting management with an awareness of capital efficiency

Under the MTBP, we have set ROIC and ROE as financial goals for fiscal 2022, and we will continue our efforts to manage with an awareness of capital efficiency going forward. In the revision of the MTBP, which we announced in May 2021, we revised the goals for both ROIC and ROE down to 3% in conjunction with the downward revision of core operating profit.

Going forward, we will focus efforts on strengthening earnings through expansion of new in-house products and streamlining management world-wide with the aim of achieving ROE of at least 10% in the late 2020s.

Finally, with regard to our shareholder return policy, there has been no change to our dividend policy, which is "a performance linked dividend hike will be considered in addition to consistent dividend payments." During the period of the MTBP, our goal for the five-year average payout ratio is 20% or higher. Based on these dividend policies, we plan to pay an interim and year-end dividend of ¥14 per share in fiscal 2021, the year ending March 21, 2022, for a total annual dividend of ¥28 (consolidated payout ratio of 27.1%), which is the same as the dividend in fiscal 2020.

Sumitomo Dainippon Pharma will continue striving to achieve sustained growth and enhancement of corporate value over the medium to long term by implementing growth investment focused on the future, with due consideration for financial soundness and capital efficiency.

# **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, 2021, in the pharmaceutical sector, R&D expenses continue to rise and competition is intensifying as the Japanese government takes further steps to curb the prices of brand-name drugs, promoting the use of generics in their stead, by, for example, expanding the scope of drugs which are subject to the off-cycle price revision. 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 activities based on the Mid-Term Business Plan 2022 ("the MTBP"), which commenced in FY2018 and will run for a total of five years to fiscal 2022. During the fiscal year under review, the COVID-19 pandemic impacted various aspects of our business activities in countries and regions where the Group operates, such as restrictions on the provision of medical information and delays in clinical studies. In response, the Group used utmost caution to avoid any delay in each stage of its activities, from procurement of raw materials to manufacturing and marketing of products, to ensure the timely delivery of drugs to patients who need them. Also, we carefully pursued business activities by placing the safety of medical professionals, business partners, employees, and other stakeholders first, by holding online interviews and using digital tools to provide medical information, among other precautions.

In Japan, the Group has sought to bolster sales of mainstay products, including Trulicity<sub>®</sub>, Equa<sup>®</sup>, EquMet<sup>®</sup>, and TRERIEF<sup>®</sup>, while at the same time focusing on the provision of medical information to achieve early market penetration of new products, including LATUDA<sup>®</sup> which was launched during the fiscal year under review.

In North America, Sunovion Pharmaceuticals Inc. (hereinafter, "Sunovion") worked to further expand sales of global strategic product LATUDA<sup>®</sup> and engaged in business activities designed to boost sales of other mainstay products and new products.

In December 2020, Myovant Sciences Ltd. (hereinafter, "Myovant"), a subsidiary of Sumitovant Biopharma Ltd. (hereinafter, "Sumitovant"), signed an agreement with Pfizer Inc. (hereinafter, "Pfizer") concerning joint development and marketing of relugolix in North America in the oncology and women's health areas. Myovant launched ORGOVYX<sup>®</sup> (generic name: relugolix) in the U.S. in January 2021, thus commencing co-promotion with Pfizer pursuant to said agreement.

Another subsidiary of Sumitovant, Urovant Sciences Ltd. (hereinafter, "Urovant") in December 2020 obtained approval for GEMTESA<sup>®</sup> (generic name: vibegron) in the U.S. In March 2021, Urovant became a wholly owned subsidiary of Sumitovant.

In China, Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. focused on marketing activities aimed at expanding sales of LATUDA<sup>®</sup> and other products amid adversities, including fewer opportunities for medical institutions to prescribe MEROPEN<sup>®</sup> due to the increased prevalence of COVID-19.

### **Operating results**

### Revenue: ¥516.0 billion (up 6.9% year-on-year)

Revenue grew as Equa<sup>®</sup> and EquMet<sup>®</sup> contributed to sales on a full-year basis in the Japan segment and LATUDA<sup>®</sup> and other products experienced sales growth while Myovant's relugolix-related revenue was recognized in the North America segment.

# Core operating profit: ¥69.6 billion (down 3.3% year-on-year)

Core operating profit decreased as a result of significant increases in selling, general and administrative expenses and research and development expenses on the core basis as expenses incurred by Sumitovant and its subsidiaries were felt throughout the year, despite an increase in gross profit on account of revenue growth.

# Operating profit: ¥71.2 billion (down 14.4% year-on-year)

Operating profit turned out to be higher than core operating profit. This is because we recorded gains from the sales of fixed assets as a result of the sale of the Company's former Ibaraki Plant, while posting a cost reversal from a decrease in the fair value of contingent consideration and impairment losses on intangible assets in an amount greater than that of the cost reversal due to the discontinued development of napabucasin for oncology and the review of business plans. Partly because a cost reversal from a decrease in the fair value of contingent consideration surpassed the amount of impairment losses on intangible assets in the previous year (fiscal year ended March 31, 2020), operating profit showed a year-on-year decrease.

# Profit before taxes: ¥77.9 billion (down 7.3% year-on-year)

Profit before taxes reached a higher number than that of operating profit as finance income surpassed finance expenses due to the recording of forex gains on account of the yen's depreciation on March 31, 2021.

### Net profit: ¥36.8 billion (up 2.5% year-on-year)

Net profit grew as income tax expenses decreased due to the absence of special factors during the fiscal year under review, such as the reversal of deferred tax assets recognized in the U.S. in the previous year.

### Net profit attributable to owners of the parent: ¥56.2 billion (up 38.0% year-on-year)

Net profit attributable to owners of the parent (less the amount of losses attributable to non-controlling shareholders from net profit) grew substantially, as losses on Sumitovant's subsidiaries were recorded throughout the year.

The ratio of the net profit attributable to owners of the parent to revenue was 10.9%.

# Financial Condition

# Summary of assets, liabilities, and equity -Assets

Non-current assets decreased by ¥44.1 billion from the previous fiscal year-end, primarily owing to a decrease in intangible assets due to depreciation and impairment losses.

Current assets increased by ¥95.7 billion from the previous fiscal year-end, primarily owing to increases in inventories and cash and cash equivalents.

As a result, total assets increased by ¥51.6 billion from the previous fiscal year-end to ¥1,308.1 billion.

### -Liabilities

Deferred revenue, which is included in other non-current liabilities, increased as a result of the conclusion of a collaborative agreement for development and commercialization by a consolidated subsidiary. Provisions saw an increase as well. Bonds and borrowings under non-current liabilities increased, and borrowings under current liabilities decreased as a result of financing by seeking long-term borrowings and issuing subordinated bonds to repay the short-term borrowings.

As a result, total liabilities increased by ¥39.3 billion from the previous fiscal year-end to ¥659.9 billion.

### -Equity

Equity attributable to owners of the parent increased by ¥47.9 billion from the previous fiscal year-end to ¥580.6 billion, primarily as a result of an increase in retained earnings. Non-controlling interests decreased by ¥35.6 billion from the previous fiscal year-end, since Sumitovant made Urovant its wholly-owned subsidiary as well as Sumitovant's subsidiaries posted losses.

As a result, total equity increased by ¥12.3 billion from the previous fiscal year-end to ¥648.2 billion.

The ratio of equity attributable to owners of the parent to total assets as of the end of the fiscal year under review was 44.4%.

### Status of cash flows

### -Net cash provided by operating activities

Cash flows provided by operating activities increased by ¥89.5 billion from the previous fiscal year-end to ¥135.6 billion, owing to factors that contributed to an increase in cash, such

as the increase in provisions, and the receipt of a lump-sum payment following the conclusion of the collaborative agreement for development and commercialization by a consolidated subsidiary, despite an increase in income taxes paid.

### -Net cash used in investing activities

Cash flows provided by investing activities amounted to ¥8.9 billion, as proceeds from sales of property, plant and equipment increased on account of the transfer of the Company's former Ibaraki Plant. Cash flows from investing activities were further bolstered as the amount of purchases decreased by ¥321.6 billion from the previous fiscal year-end with the absence of the purchase of investments as a result of the acquisition of shares of Roivant Sciences Ltd. (hereinafter, "Roivant") and the payment for the acquisition of control of Sumitovant and its subsidiaries, all of which were posted in the previous fiscal year.

### -Net cash provided by financing activities

Cash flows used in financial activities amounted to ¥57.2 billion. This was chiefly because of a decrease in proceeds by ¥288.3 billion from the previous fiscal year as the Company sought funds from short-term borrowings for the payment of the consideration for the Strategic Alliance with Roivant in the previous fiscal year. Conversely, in the fiscal year under review, the Company repaid the short-term borrowings by financing with long-term borrowings and issuance of subordinated bonds and saw an increase in payments for acquisition of interest in a subsidiary from non-controlling interests due to acquisition of Urovant.

#### -Cash and cash equivalents

As a result of the above, the balance of cash and cash equivalents as of March 31, 2021 was ¥193.7 billion, which represents an increase of ¥92.0 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 surpluses 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 its continuous effort to further increase its corporate value, the Company remains committed to

# **Operating Results and Financial Condition, and Business Risks**

establishing a solid management base and a strong financial position, while making proactive investments for sustained business growth. In the MTBP covering the period, the Company aims for a five-year average dividend 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 an annual dividend of 28 yen per share on a full-year basis.

The Company expects a decrease in profit for the fiscal year ending March 31, 2022 compared with the fiscal year under review. Given the importance of maintaining a stable dividend payment, however, the Company plans to pay an annual dividend of 28 yen per share, which comprises an interim dividend of 14 yen per share and a year-end dividend of another 14 yen per share.

### Forecasts for the year ending March 31, 2022

In Japan, revenue is forecasted to decrease slightly as the impacts of the NHI drug price revisions and declines in sales of long-listed products may not be offset by our efforts to expand sales of LATUDA<sup>®</sup> and Trulicity<sub>®</sub>. In North America, revenue is forecasted to increase substantially as we expect sales expansion of LATUDA<sup>®</sup>, ORGOVYX<sup>®</sup> (by Myovant), GEMTESA<sup>®</sup>, and MYFEMBREE<sup>®</sup> (relugolix combination tablet), which was launched by Myovant in June 2021, as well as income from industrial property rights through a new alliance. Consolidated revenue is thus expected to increase by ¥62.0 billion year-on-year to ¥578.0 billion.

Core operating profit is forecasted to decrease by ¥5.6 billion year-on-year to ¥64.0 billion, and operating profit is expected to decrease by ¥10.2 billion year-on-year to ¥61.0 billion, as a result of expected increases in patent amortization, as well as in marketing expenses in North America following the launch of full-fledged marketing of new products there, although we expect gross profit to increase on account of revenue growth. Partly because we do not expect forex gains, which were recorded in the fiscal year under review, net profit attributable to owners of the parent for the fiscal year ending March 31, 2022 is forecasted to decrease by ¥15.2 billion year-on-year to ¥41.0 billion.

### **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, 2021. 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.

Please see page 14 for details on opportunities and risks for each stage of the value chain.

# Risk relating to research and development of new products

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 40% 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 MTBP, 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, healthcare system changes are being implemented with the aim of controlling pharmaceutical expenses, including an expansion in centralized drug purchasing by governments. The direction that each country's healthcare system reforms 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 the Ministerial Ordinance on Good Vigilance Practice (GVP) for Drugs, Quasi-drugs, Cosmetics, Medical Devices, and Cellular and Tissue-based Products.

#### **Risks relating to quality**

The Group manufactures and subcontracts the manufacturing of 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 global manufacture and distribution of the Group's products are conducted in accordance with laws and regulations related to pharmaceuticals, including Good Manufacturing Practice (GMP) and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guidelines, and have undergone rigorous inspections 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 carries out regular audits of these manufacturing facilities and has confirmed that there are no serious quality issues or violations of laws and regulations. Furthermore, at facilities that manufacture global products, we have in place high

# **Operating Results and Financial Condition, and Business Risks**

levels of facility design and quality assurance systems that conform to strict global quality standards and have been audited by overseas alliance partners.

### 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, other disasters, or spread of infectious diseases 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, 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. The Group strives to avoid interest rate risk by optimizing capital procurement through a combination of fixed and variable interest rates. 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 and we make short-term loans to our parent company for purposes such as raising capital efficiency. The Company's policy is to continue these transactions and other ties with the parent company. However, changes in these agreements, including changes in the transaction terms specified therein, could have a significant and negative impact on the Group's operating results, 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 business activities, the Company has formulated Risk Management Rules 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, and additional obligations to reduce environmental impact, it could have a significant and negative impact on the Group's operating results, etc. Additionally, given the issue of global climate change, operations at our facilities inside or outside Japan, or at our suppliers, may be impacted due to large-scale typhoons, localized torrential downpours, or the emergence of other water-related risks, and, raw material and utility costs may rise due to stronger regulations being adopted, such as carbon taxes. Either of these situations 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, as well as the Suzhou Plant (China), 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. We strive to disclose information on climate change and water-related risks and opportunities following the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD).

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, 2021 and 2020			Millions of ye
	Note	2020	2021
Revenue	4, 5	¥482,732	¥515,952
Cost of sales		129,673	137,773
Gross profit		353,059	378,179
Selling, general and administrative expenses	6	154,348	190,373
Research and development expenses		115,112	132,682
Other income	7	1,404	17,662
Other expenses	8	1,764	1,562
Operating profit		83,239	71,224
Finance income	9	3,568	9,213
Finance costs	9	2,860	2,586
Profit before taxes		83,947	77,851
Income tax expenses	10	48,029	41,022
Net profit		35,918	36,829
Net profit attributable to:			
Owners of the parent		40,753	56,219
Non-controlling interests		(4,835)	(19,390)
Net profit total		35,918	36,829
Earnings per share (yen)			
Basic earnings per share	11	102.58	141.50

# **Consolidated Statement of Comprehensive Income**

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2021 and 2020

Years Ended March 31, 2021 and 2020			Millions of yer
	Note	2020	2021
Net profit		¥35,918	¥36,829
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	11,350	(7,621)
Remeasurements of defined benefit liability (asset)	12	46	6,330
Items that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of foreign operations	12	(7,386)	5,367
Cash flow hedges	12	(23)	102
Total other comprehensive income		3,987	4,178
Total comprehensive income		39,905	41,007
Total comprehensive income attributable to:			
Owners of the parent		45,670	61,008
Non-controlling interests		(5,765)	(20,001)
Total comprehensive income		39,905	41,007

(Note) During the year ended March 31, 2021, the Company finalized the purchase price allocation for the assets acquired and the liabilities assumed related to the strategic alliance with Roivant. Therefore, the Consolidated Statement of Comprehensive Income for the year ended March 31, 2020 was retrospectively adjusted. The details are presented in Note 34. Business Combinations and Acquisition of Non-Controlling Interests.

# **Consolidated Statement of Financial Position**

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries

Years Ended March 31, 2021 and 2020	Milli			
	Note	2020	2021	
Assets				
Non-current assets				
Property, plant and equipment	14, 17	¥ 65,748	¥ 64,966	
Goodwill	15	173,464	176,492	
Intangible assets	16	421,029	383,406	
Other financial assets	18, 30	200,923	193,035	
Income taxes receivables		—	6,726	
Other non-current assets		4,173	3,516	
Deferred tax assets	10	27,107	20,191	
Total non-current assets		892,444	848,332	
Current assets				
Inventories	19	79,368	92,215	
Trade and other receivables	20, 30	134,491	135,866	
Other financial assets	18, 30	28,717	29,480	
Income taxes receivables		5,877	194	
Other current assets		9,624	8,342	
Cash and cash equivalents	21	101,708	193,698	
Subtotal		359,785	459,795	
Assets held for sale	13	4,305	-	
Total current assets		364,090	459,795	
Fotal assets		1,256,534	1,308,127	
iabilities and equity		, ,		
iabilities				
Non-current liabilities				
Bonds and Borrowings	22, 30	25,020	263,859	
Other financial liabilities	17, 24, 30	41,306	21,404	
Retirement benefit liabilities	27	23,870	15,069	
Other non-current liabilities	26	7,212	53,046	
Deferred tax liabilities	10	26,768	28,424	
Total non-current liabilities	10	124,176	381,802	
Current liabilities		124,170	501,002	
Borrowings	22, 30	272,960	9,960	
Trade and other payables	23, 30	62,251	64,638	
Other financial liabilities			23,34	
	17, 24, 30	13,906		
Income taxes payable	25	22,637	24,511	
Provisions Other current liabilities	25 26	84,644	99,851 55 844	
Other current liabilities Total current liabilities	20	40,100	55,846	
Fotal liabilities		496,498	278,147	
		620,674	659,949	
Equity	20	22 400	22 400	
Share capital	29	22,400	22,400	
Capital surplus	29	17,837	15,855	
Treasury shares	29	(677)	(679	
Retained earnings	29	457,330	508,677	
Other components of equity	29	35,780	34,317	
Equity attributable to owners of the parent		532,670	580,570	
Non-controlling interests		103,190	67,608	
Total equity		635,860	648,178	
Total liabilities and equity		¥1,256,534	¥1,308,127	

(Note) During the year ended March 31, 2021, the Company finalized the purchase price allocation for the assets acquired and the liabilities assumed related to the strategic alliance with Roivant. Therefore, the Consolidated Statement of Financial Position as of March 31, 2020 was retrospectively adjusted. The details are presented in Note 34. Business Combinations and Acquisition of Non-Controlling Interests.

# **Consolidated Statement of Changes in Equity**

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries

Years Ended March 31, 2021 and 2020		Equity attributable to owners of the parent M						
						Other components	s of equity	
No	ote	Share capital	Capital surplus	Treasury shares	Retained earnings	Net gain (loss) on revaluation of financial assets measured at fair value through other comprehensive income	Remeasurements of defined benefit liability (asset)	
Balance as of April 1, 2019		¥22,400	¥15,861	¥(674)	¥431,799	¥32,611	¥ —	
Net profit		—	—	—	40,753	—	—	
Other comprehensive income 1	2	—	—	—	—	11,350	46	
Total comprehensive income		—	—	—	40,753	11,350	46	
Purchase of treasury shares 2	9	—	—	(3)	—	—	—	
Dividends 2		—	—	—	(13,111)	—	—	
Acquisition of subsidiaries		—	—	—	—	—	—	
Transactions with non-controlling interests		—	1,976	—	—	—	—	
Reclassification from other components of equity to retained earnings		—	—	—	(2,111)	2,157	(46)	
Total transactions with owners		—	1,976	(3)	(15,222)	2,157	(46)	
Balance as of March 31, 2020		¥22,400	¥17,837	¥(677)	¥457,330	¥46,118	¥ —	
Net profit		—	—	_	56,219	—	—	
Other comprehensive income 1	2	—	—	—	—	(7,621)	6,330	
Total comprehensive income		—	—	—	56,219	(7,621)	6,330	
Purchase of treasury shares 2	9	—	—	(2)	_	—	_	
Dividends 2	9	—	—	—	(11,124)	_		
Transactions with non-controlling interests		—	(1,982)	—	—	—	—	
Reclassification from other components of equity to retained earnings		—	—	—	6,252	78	(6,330)	
Other increase / decrease		—	—	—	—	—	—	
Total transactions with owners		—	(1,982)	(2)	(4,872)	78	(6,330)	
Balance as of March 31, 2021		¥22,400	¥15,855	¥(679)	¥508,677	¥38,575	¥ —	

		Equity attributable to owners of the parent					Millions of yen	
		Other co	mponents of eq	uity			sts Total equity	
	Note	Exchange differences on translation of foreign operations	Cash flow hedges	Total	Total	Non-controlling interes		
Balance as of April 1, 2019		¥ (3,853)	¥ (6)	¥28,752	¥498,138	¥ —	¥498,138	
Net profit		—	—	—	40,753	(4,835)	35,918	
Other comprehensive income	12	(6,456)	(23)	4,917	4,917	(930)	3,987	
Total comprehensive income		(6,456)	(23)	4,917	45,670	(5,765)	39,905	
Purchase of treasury shares	29	—	—	—	(3)	—	(3)	
Dividends	29	—	—	—	(13,111)	—	(13,111)	
Acquisition of subsidiaries		—	—	—	—	111,568	111,568	
Transactions with non-controlling interests		—	—	—	1,976	(2,613)	(637)	
Reclassification from other components of equity to retained earnings		—	—	2,111	—	—	_	
Total transactions with owners		—		2,111	(11,138)	108,955	97,817	
Balance as of March 31, 2020		¥(10,309)	¥(29)	¥35,780	¥532,670	¥103,190	¥635,860	
Net profit		—	—	—	56,219	(19,390)	36,829	
Other comprehensive income	12	5,978	102	4,789	4,789	(611)	4,178	
Total comprehensive income		5,978	102	4,789	61,008	(20,001)	41,007	
Purchase of treasury shares	29	—	—	—	(2)	—	(2)	
Dividends	29	—	—	—	(11,124)	—	(11,124)	
Transactions with non-controlling interests		—	—	—	(1,982)	(15,630)	(17,612)	
Reclassification from other components of equity to retained earnings		—	—	(6,252)	—	—	_	
Other increase/decrease		—	_		—	49	49	
Total transactions with owners		—	—	(6,252)	(13,108)	(15,581)	(28,689)	
Balance as of March 31, 2021		¥ (4,331)	¥ 73	¥34,317	¥580,570	¥ 67,608	¥648,178	

(Note) During the year ended March 31, 2021, the Company finalized the purchase price allocation for the assets acquired and the liabilities assumed related to the strategic alliance with Roivant. Therefore, the Consolidated Statement of Changes in Equity as of March 31, 2020 was retrospectively adjusted. The details are presented in Note 34. Business Combinations and Acquisition of Non-Controlling Interests.

# **Consolidated Statement of Cash Flows**

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2021 and 2020

Years Ended March 31, 2021 and 2020			Millions of yen	
	Note	2020	2021	
Cash flows from operating activities				
Net profit		¥ 35,918	¥ 36,829	
Depreciation and amortization		17,365	22,673	
Impairment losses		35,196	35,720	
Changes in fair value of contingent consideration		(48,474)	(22,463)	
Loss (gain) on sales of property, plant and equipment		(77)	(16,731)	
Interest and dividend income		(3,564)	(1,153)	
Interest expenses		699	2,436	
Income tax expenses		48,029	41,022	
(Increase) decrease in trade and other receivables		(16,374)	185	
(Increase) decrease in inventories		(14,354)	(10,039)	
Increase (decrease) in trade and other payables		15,241	(320)	
Increase (decrease) in unearned revenue		—	51,067	
Increase (decrease) in other financial liabilities		912	12,001	
Increase (decrease) in retirement benefits liabilities		338	288	
Increase (decrease) in provisions		(5,703)	13,145	
Others, net		4,601	7,042	
Subtotal		69,753	171,702	
Interest received		2,686	221	
Dividends received		1,123	942	
Interest paid		(1,526)	(2,229)	
Income taxes paid		(25,908)	(35,035)	
Net cash provided by operating activities		46,128	135,601	
Cash flows from investing activities		,		
Purchase of property, plant and equipment		(7,722)	(6,048)	
Proceeds from sales of property, plant and equipment		769	21,520	
Purchase of intangible assets		(5,629)	(4,758)	
Purchase of investments		(112,494)	(9,366)	
Proceeds from sales and redemption of investments		1,623	8,141	
Payments for acquisition of control of subsidiaries		(205,774)		
Net decrease (increase) in short-term loan receivables		16,520	(839)	
Others, net		23	225	
Net cash provided by (used in) investing activities		(312,684)	8,875	
Cash flows from financing activities		(312,001)	6,675	
Net increase (decrease) in short-term borrowings	22	270,000	(265,000)	
Proceeds from long-term borrowings	22		125,000	
Repayments of long-term borrowings	22	(19,623)	(2,960)	
Proceeds from issuance of corporate bonds	22	(15,025)	118,927	
Repayments of lease liabilities	22	(4,837)	(4,727)	
Dividends paid	<u> </u>	(4,837)	(11,120)	
Payments for acquisition of interest in a subsidiary from non-controlling interests		(13,106) (1,350)	(11,120) (19,300)	
Others, net				
Net cash provided by (used in) financing activities		(3)	(57.215)	
Net increase (decrease) in cash and cash equivalents		231,081	(57,215)	
	21	(35,475)	87,261	
Cash and cash equivalents at beginning of year	21	137,296	101,708	
Effect of exchange rate changes on cash and cash equivalents	24	(113)	4,729	
Cash and cash equivalents at end of year	21	¥101,708	¥193,698	

# **Notes to Consolidated Financial Statements**

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2021 and 2020

### **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, 2021. The Company's Consolidated Financial Statements comprise the Company and its subsidiaries (the "Group"), its interests in associates. The Group is primarily involved in pharmaceutical business. The details of the main business are presented in Note 4 Operating Segments. The registered address of the Company's Head Office and its main places of business are presented on the Company's website (URL https://www.ds-pharma.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 24, 2021 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 the fiscal year ending March 31, 2022.

- Main accounting estimates, judgments, and assumptions are summarized as follows:
- Goodwill and intangible assets (Note 15 and 16)
- Financial assets measured at fair value through other comprehensive income (Note 30)
- Provisions (Note 25)
- Fair value of contingent consideration (Note 30)

### (5) Changes in Presentation

### (Consolidated Statement of Cash Flows)

"Loss (gain) on sales of property, plant and equipment" and "Increase (decrease) in other financial liabilities", which were included in "Others, net" under "Cash flows from operating activities" in the year ended March 31, 2020, are presented separately in the year ended March 31, 2021 due to the increase in amount from materiality perspective. To reflect this change in presentation, certain reclassifications have been made to the consolidated financial statements for the year ended March 31, 2020 to conform to the presentation for the year ended March 31, 2021.

As a result, "Others, net" under "Cash flows from operating activities" in the year ended March 31,

2020 amounting to ¥5,436 million was reclassified into "Loss (gain) on sales of property, plant and equipment" of (¥77 million), "Increase (decrease) in other financial liabilities" of ¥912 million, and "Others, net" of ¥4,601 million.

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

New or revised Standards and Interpretations that were issued by the date of approval of the consolidated financial statements but were not yet early adopted by the Group are as follows. The effect on the Group's consolidated financial statements is currently being evaluated, and cannot be estimated for the time being.

New or revised Standards and Interpretations		Mandatory application (Hereafter, Starting Year)	Adoption by the Group	Overview of introduction or revision
IFRS 7 IFRS 9	Financial Instruments: Disclosure Financial Instruments	January 1, 2021	Year ending March 31, 2022	Interest Rate Benchmark Reform - Phase 2 Amendments related to the effects on financial reporting arising from the replacement of existing interest rate benchmark with an alternative interest rate benchmark.

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

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

### 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.

# **Notes to Consolidated Financial Statements**

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2021 and 2020

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.

4. Joint Control

Joint Control is the contractually agreed sharing of control of an arrangement, which exists only when decisions about the relevant activities require the unanimous consent of the parties sharing control. An investment in joint arrangement are classified as a joint operation or a joint venture according to the rights and obligations of the parties to the arrangement. A joint operation is a joint arrangement whereby the parties that have joint control of the arrangement have rights to the assets, and obligations for the liabilities, relating to the arrangement. A joint venture is a joint arrangement whereby the parties that have joint control of the arrangement have rights to the arrangement whereby the parties that have joint control of the arrangement.

When the Company holds an interest in a joint operation, its share of assets, liabilities, revenues, and expenses related to the joint operation are included in similar accounts, respectively.

### (2) Foreign currency translations

### 1. Foreign currency transactions

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

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

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

### 2. Foreign operations

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

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

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

#### (3) Revenue

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

Step 1: Identify the contract with a customer

Step 2: identify the performance obligations in the contract

Step 3: Determine the transaction price

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

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

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

#### 1. Sales of products

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

2. Revenue arising from intellectual property rights

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

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

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

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

#### (4) Joint development and joint sales

The Group has entered into a development and commercialization agreement related to the Group's developed products and finished goods with its alliance partner.

In this case, revenue from pharmaceutical sales (sales of goods) is recognized as sales revenue, and the Group's relevant expenses are recognized as cost of sales, selling, general and administrative expenses, and research and development expenses, and presented in gross basis. Also, the Group recognizes expenses paid to its alliance partner for equally sharing profit in cost of sales, selling, general and administrative expenses, and research and development expenses according to the nature.

The details of the major agreements among these are presented in Note 35. Joint Development and Joint Sales.

#### (5) 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.

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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.

#### (6) 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.

#### (7) 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.

#### (8) 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-ofuse 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.

#### (9) 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.

#### (10) 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

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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.

#### (11) 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 less 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.

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

#### (iii) Derecognition

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

#### (iv) Impairment

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

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

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

# 2. Financial liabilities

(i) Initial recognition and measurement

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

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

Financial liabilities which were designated to be measured at fair value through profit or loss. (b) Financial liabilities measured at amortized cost

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> 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 recognizion 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.

#### (13) 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.

#### (14) 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.

#### (15) Employee benefits

1. Post-retirement benefits

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

(i) Defined benefit plan

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

(ii) Defined contribution plan

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

2. Other long-term employee benefits

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

3. Short-term employee benefits

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

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

#### (16) 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.

#### (17) 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

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a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the liability.

#### (18) 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.

### (19) 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 Note 3 Significant

Accounting Policies.

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

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

## 1. Year ended March 31, 2020

	Millions of yen								
	2020								
		Rep	oortable segmen	ts					
		Phar	maceutical busir	iess		Other business (Note)	Total		
	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.

# 2. Year ended March 31, 2021

	Millions of yen							
		2021						
		Rep	oortable segmen	ts				
		Phar	maceutical busir	iess		Other business (Note)	Total	
	Japan	North America	China	Other Regions	Subtotal			
Revenues from external customers, etc	¥ 152,497	¥ 281,493	¥ 27,831	¥ 17,233	¥ 479,054	¥ 36,898	¥ 515,952	
Inter-segment revenues	70	_	—	_	70	46	116	
Total	152,567	281,493	27,831	17,233	479,124	36,944	516,068	
Segment profit (Core segment profit)	24,284	116,881	13,238	8,693	163,096	3,574	166,670	
Other items								
Depreciation and amortization	5,710	11,363	838	910	18,821	304	19,125	
Impairment losses	128	35,592	_	_	35,720	_	35,720	

(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.

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

The details of reconciliation are as follows:

	Millions of yen			
Revenue	Year ended March 31, 2020	Year ended March 31, 2021		
Total of reportable segments	¥ 445,439	¥ 479,124		
Revenue of other business	37,422	36,944		
Elimination of inter-segment revenue	(129)	(116)		
Revenue on the consolidated financial statements	¥ 482,732	¥ 515,952		

	Millions of yen			
Profit	Year ended March 31, 2020	Year ended March 31, 2021		
Total of reportable segments	¥ 161,216	¥ 163,096		
Segment profit of other business	3,202	3,574		
Elimination of inter-segment profit	19	22		
Research and development expenses (Note)	(92,607)	(97,082)		
Gains on business transfers	157	_		
Others	(5)	(27)		
Core operating profit	71,982	69,583		
Change in fair value of contingent consideration	48,474	22,463		
Impairment losses	(35,196)	(35,720)		
Other income	1,252	17,689		
Other expenses	(1,764)	(1,562)		
Others	(1,509)	(1,229)		
Operating profit in the consolidated financial statements	¥ 83,239	¥ 71,224		

(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								
	Total of report	able segments	Other b	usiness	Adjust	ments	Amount in the consolidated financial statements			
Other items	Year ended March 31, 2020	Year ended March 31, 2021	Year ended March 31, 2020	Year ended March 31, 2021	Year ended March 31, 2020	Year ended March 31, 2021	Year ended March 31, 2020	Year ended March 31, 2021		
Depreciation and										
amortization	¥ 13,603	¥ 18,821	¥ 290	¥ 304	¥ 3,472	¥ 3,548	¥ 17,365	¥ 22,673		

### (4) Revenues

The details of revenues from external customers are as follows:

The details of feverices from external customers are as follows.	Millions of yen			
	Year ended March 31, 2020	Year ended March 31, 2021		
Sale of goods	¥ 474,543	¥ 503,788		
Revenue arising from intellectual property rights	3,665	7,924		
Other	4,524	4,240		
Total	¥ 482,732	¥ 515,952		

## (5) Information by product and service

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

	Million	s of yen
	Year ended March 31, 2020	Year ended March 31, 2021
Pharmaceuticals	¥ 445,363	¥ 479,054
Others	37,369	36,898
Total	¥ 482,732	¥ 515,952

#### (6) Geographic information

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

	Million	s of yen
	Year ended March 31, 2020	Year ended March 31, 2021
Japan	¥ 180,678	¥ 192,608
North America	261,630	280,437
U.S.A. in North America	256,427	275,594
Others	40,424	42,907
Total	¥ 482,732	¥ 515,952

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:

	Million	s of yen
	As of March 31, 2020	As of March 31, 2021
Japan	¥ 67,263	¥ 65,979
North America	594,629	566,701
U.S.A. in North America	593,065	565,215
Others	2,522	2,426
Total	¥ 664,414	¥ 635,106

(Note) During the year ended March 31, 2021, the Company finalized the purchase price allocation for the assets acquired and the liabilities assumed related to the strategic alliance with Roivant. Therefore, non-current assets by location as of March 31, 2020 was retrospectively adjusted. The details are presented in Note 34. Business Combinations and Acquisition of Non-Controlling Interests.

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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:

		Millions of yen				
	Reportable segment	Year ended March 31, 2020	Year ended March 31, 2021			
McKesson Corporation	North America	¥ 87,812	¥ 95,732			
Cardinal Health Inc.	North America	75,502	82,143			
AmerisourceBergen Corporation	North America	65,110	71,767			

### 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:

	n 31, 2020				Millions of yen					
			eportable segmer			Other business (Note)	Total	Including revenue	reve	uding enue
	Japan	North America	China	Other Regions	Subtotal		Total	from contracts with customers		
Sales of goods	¥ 135,215	¥ 261,080	¥ 28,389	¥ 12,490	¥ 437,174	¥ 37,369	¥ 474,543	¥ 474,543	¥	_
Revenue arising from intellectual property rights	154	1,215	_	2,296	3,665	_	3,665	3,665		
Other	4,306		218		4,524		4,524	4,524		_
「otal	¥ 139,675	¥ 262,295	¥ 28,607	¥ 14,786	¥ 445,363	¥ 37,369	¥ 482,732	¥ 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.

Year ended March	31, 2021				Millions of yen					
		Reportable segments Pharmaceutical business				Other business (Note 1)	Total	Including revenue from contracts	Including revenue from other sources	
	Japan	North America	China	Other Regions	Subtotal	(1010-1)			with customers	(Note 2)
Sales of goods	¥ 150,255	¥ 274,015	¥27,596	¥ 15,024	¥ 466,890	¥ 36,898	¥ 503,788	¥ 503,788	¥ —	
Revenue arising										
from intellectual										
property rights	791	4,924		2,209	7,924		7,924	7,924		
Other	1,451	2,554	235	_	4,240	_	4,240	1,868	2,372	
Total	¥ 152,497	¥ 281,493	¥ 27,831	¥ 17,233	¥ 479,054	¥ 36,898	¥ 515,952	¥ 513,580	¥ 2,372	

(Note) 1. 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. Revenue from other sources is sales revenue from contracts with joint partners in which the counterparty is not deemed as a customer. The details are presented in Note 35 Joint Development and Joint Sales.

#### (2) Contract balances

Contract balances arising from contracts with customers are as follows:

	Million	Millions of yen		
	As of March 31, 2020	As of March 31, 2021		
Receivables from contracts with customers				
Accounts receivable and notes receivable	¥ 128,478	¥ 127,260		
Contract assets	970	1,310		
Contract liabilities	4,352	2,011		

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 related to these technology licensing-out agreements are satisfied.

Among revenue recognized during the year ended March 31, 2021, ¥2,539 million was included in contract liability balance at the beginning of the fiscal year ended March 31, 2021. Among revenue recognized during the year ended March 31, 2020, there was none which was included in contract liability balance at the beginning of the fiscal year ended March 31, 2020. Also, there are no significant amounts of revenue recognized during the year ended March 31, 2020 and 2021 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 fulfill 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, 2020	Year ended March 31, 2021	
Salaries and bonuses	¥ 65,753	¥ 77,437	
Retirement benefit expenses	5,160	5,125	
Advertising and promotion expenses	37,745	37,362	
Depreciation and amortization	11,272	16,707	
Impairment losses	12,102	151	
Change in fair value of contingent consideration (Note)	(48,474)	(22,463)	
Others	70,790	76,054	
Total	¥ 154,348	¥ 190,373	

(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 30 Financial Instruments.

# 7. Other Income

The details of other operating income are as follows:

	Millions of yen		
	Year ended March 31, 2020	Year ended March 31, 2021	
Gain on sale of property, plant and equipment (Note)	¥ 317	¥ 16,925	
Others	1,087	737	
Total	¥ 1,404	¥ 17,662	

(Note) Gain on sale of property, plant and equipment in the year ended March 31, 2021 includes gain on sale of the former Ibaraki Plant amounting ¥16,725 million.

# 8. Other Expenses

The details of other operating expenses are as follows:

	Millions	Millions of yen		
	Year ended March 31, 2020	Year ended March 31, 2021		
Donation	¥ 772	¥ 1,072		
Others	992	490		
Total	¥ 1,764	¥ 1,562		

## 9. Finance Income and Finance Expenses

# (1) Finance income

The details of finance income are as follows:

	Millions of yen	
	Year ended March 31, 2020	Year ended March 31, 2021
Interest income		
Financial assets at amortized cost	¥ 2,441	¥ 211
Dividend income		
Financial asset at fair value through other comprehensive income	e 1,123	942
Exchange gain (net)	_	8,037
Others	4	23
Total	¥ 3,568	¥ 9,213

# (2) Finance costs

The details of finance costs are as follows:

	Millions of yen		
	Year ended March 31, 2020	Year ended March 31, 2021	
Interest expenses			
Financial liabilities at amortized cost	¥ 699	¥ 2,436	
Exchange loss (net)	1,134		
Others	1,027	150	
Total	¥ 2,860	¥ 2,586	

# 10. Deferred Income Taxes and Income Tax Expenses

## (1) Deferred Income Taxes

 Deferred tax assets and liabilities on the Consolidated Statement of Financial Position. The details of deferred tax assets and liabilities on the Consolidated Statement of Financial Position are as follows:

	Million	Millions of yen		
	As of March 31, 2020	As of March 31, 2021		
Deferred tax assets	¥ 27,107	¥ 20,191		
Deferred tax liabilities	26,768	28,424		
Net deferred tax assets	¥ 339	¥ (8,233)		

During the year ended March 31, 2021, the Company finalized the purchase price allocation for the assets acquired and the liabilities assumed related to the strategic alliance with Roivant. Therefore, the balance of deferred tax liabilities as of March 31, 2020 was adjusted retrospectively. The details are presented in Note 34. Business Combinations and Acquisition of Non-Controlling Interests.

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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:

Year 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		(37,166)	(49,015)
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)	—	10,396	16,723
Tax credits	7,022	(6,673)		(145)	204
Undistributed profits of foreign subsidiaries	(624)	(286)			(910)
Others	3,570	(470)		(150)	2,950
Total	¥ 50,719	¥ (18,362)	¥ (4,996)	¥ (27,022)	¥ 339

(Note) Others mainly include exchange differences on translation of foreign operations and effects arising from business combinations.

Year ended March 31, 2021

			Millions of yen		
	As of April 1, 2020	Recognized in profit or loss	Recognized in other comprehensive income	Others (Note)	As of March 31, 2021
Outsourced research expenses	¥ 9,346	¥ (3,781)	¥ —	¥ —	¥ 5,565
Inventories	22,656	51	—	(31)	22,676
Property, plant and equipment	1,832	135	_	67	2,034
Intangible assets	(49,015)	7,578	_	(518)	(41,955)
Other financial assets	(17,783)	(1)	3,122	(3,402)	(18,064)
Accrued expenses and provisions	6,062	(1,306)		4	4,760
Retirement benefits	8,274	45	(2,776)	(4)	5,539
Tax loss carryforwards	16,723	(5,765)	_	41	10,999
Tax credits	204	—	_	4	208
Undistributed earnings of foreign subsidiaries	(910)	(70)	_		(980)
Others	2,950	(1,949)	_	(16)	985
Total	¥ 339	¥ (5,063)	¥ 346	¥ (3,855)	¥ (8,233)

(Note) Others mainly include exchange differences on translation of foreign operations and effects arising from sale of financial assets measured at fair value through other comprehensive income during the current fiscal year.

# 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:

	Million	Millions of yen		
	As of March 31, 2020	As of March 31, 2021		
Tax loss carryforwards	¥ 20,617	¥ 36,407		
Tax credit carryforwards	11,968	18,512		
Deductible temporary differences	¥ 17,457	¥ 20,430		

### 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, 2020	As of March 31, 2021	
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	20,617	36,407	
Total	¥ 20,617	¥ 36,407	

(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, 2020	As of March 31, 2021	
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	11,968	18,512	
Total	¥ 11,968	¥ 18,512	

#### 5. Recoverability of deferred tax assets

Deferred tax assets as of March 31, 2021 was ¥69,252 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, 2020 and 2021.

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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, 2020	Year ended March 31, 2021	
Current tax expenses (Note 1)	¥ 29,667	¥ 35,959	
Deferred tax expense			
Origination and reversal of temporary differences	(4,978)	5,063	
Assessment of the recoverability of deferred tax assets (Note 2)	23,340	_	
Subtotal	18,362	5,063	
Total	¥ 48,029	¥ 41,022	

(Note) 1. On March 27, 2020, "The Coronavirus Aid, Relief, and Economic Security (CARES) Act" (the "CARES Act") was enacted in the United States of America. The main provisions of the Act that impact on the year ended March 31, 2020 and 2021 are as follows:

(Carryback of net operating tax losses)

The CARES 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 effects arising from carryback of net operating tax losses of (¥4,040 million) (profit) for the year ended March 31, 2020 and (¥2,344 million) (profit) for the year ended March 31, 2021 were included in the current tax expenses in the year ended March 31, 2021.

2. This is due to review of the recoverability of deferred tax assets in a certain subsidiary of the Company for the year ended March 31, 2020.

# 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, 2020 and 2021. The normal statutory tax rate based on these taxes is 30.6% for the years ended March 31, 2020 and 2021. However, overseas subsidiaries are subject to income taxes in their respective countries of domicile.

	Year ended March 31, 2020	Year ended March 31, 2021
Normal statutory tax rate	30.6%	30.6%
Permanent non-deductible expenses such as entertainment expenses	1.6%	1.3%
Permanent non-taxable income such as dividend received	(0.1%)	(0.1%)
Tax credit for research and development expenses	(10.2%)	(7.6%)
Changes in unrecognized deferred tax assets	41.9%	11.3%
Difference of subsidiaries' applicable income tax rates	14.1%	28.5%
Changes in tax effect of undistributed earnings of subsidiaries	0.3%	0.1%
Effect of change in fair value of contingent consideration	(15.5%)	(8.2%)
Effect of the CARES Act	(4.8%)	(3.0%)
Others	(0.7%)	(0.2%)
Effective tax rate	57.2%	52.7%

# **11. Earnings per Share**

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

	Year ended March 31, 2020	Year ended March 31, 2021
The basis for calculation of basic earnings per share		
Net profit attributable to owners of the parent (Millions of yen)	¥ 40,753	¥ 56,219
Amounts not attributable to ordinary shareholders of the paren (Millions of yen)	t	_
Net profit used to calculate basic earnings per share		
(Millions of yen)	40,753	56,219
Weighted average number of ordinary shares		
(Thousands of shares)	397,295	397,294
Earnings per share		
Basic earnings per share (Yen)	102.58	141.50

(Note) Diluted earnings per share is not disclosed as there are potential shares that have an antidilutive effect for the years ended March 31, 2020 and 2021. These potential shares are stock options issued by certain subsidiaries. The details are presented in Note 28, Share-based payments.

# 12. Other Comprehensive Income

The movement of other comprehensive income is as follows:

	Millions of yen		
	Year ended March 31, 2020	Year ended March 31, 2021	
Net gain (loss) on revaluation of financial assets measured at fair value through other comprehensive income			
Amounts arising during the year	¥ 16,336	¥ (10,797)	
Tax effect	(4,986)	3,176	
Net gain (loss) on revaluation of financial assets measured at fair value through other comprehensive income	11,350	(7,621)	
Remeasurements of defined benefit liability (asset)			
Amounts arising during the year	68	9,106	
Tax effect	(22)	(2,776)	
Remeasurements of defined benefit liability (asset)	46	6,330	
Exchange differences on translation of foreign operations			
Amounts arising during the year	(7,386)	5,367	
Exchange differences on translation of foreign operations	(7,386)	5,367	
Cash flow hedges			
Amounts arising during the year	(35)	156	
Tax effect	12	(54)	
Cash flow hedges	(23)	102	
Total	¥ 3,987	¥ 4,178	

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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:

	Million	Millions of yen		
	As of March 31, 2020	As of March 31, 2021		
Assets held for sale				
Property, plant and equipment	¥ 4,305	¥ —		
Total	¥ 4,305	¥ —		

Property, plant and equipment related to the former Ibaraki Plant held by the Company are classified as non-current assets held for sale as of March 31, 2020. Sales of these assets were completed for the year ended March 31, 2021.

# 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 f vehicles	Tools, urniture and fixtures		Construction in progress	Right-of -use assets	Total
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 combination	ıs 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
Additions	773	487	466	—	4,600	4,136	10,462
Transfer from construction in progress	1,079	2,444	1,701	—	(5,224)	—	—
Sales and disposals	(6,988)	(8,154)	(1,655)	_	(27)	(1,691)	(18,515)
Foreign currency translation differences	313	185	177	7	12	237	931
Others	(147)	31	2	_	127	(68)	(55)
Balance as of March 31, 2021	¥ 75,438	¥ 55,771	¥ 29,474	¥ 4,838	¥ 1,409	¥ 20,855	¥ 187,785

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_	Millions of yen						
	Buildings and structures	Machinery and vehicles	Tools, furniture and fixtures		onstruction n progress	Right-of -use assets	Total
Balance as of April 1, 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	5 (73)	_	—	(661)	(188)
Balance as of March 31, 2020	(48,650)	(52,569)	) (23,814)	(64)	(27)	(4,090)	(129,214)
Depreciation	(2,413)	(1,947)	) (2,050)	_	_	(4,224)	(10,634)
Impairment losses	_			_	(128)	_	(128)
Sales and disposals	6,971	8,074	1,623	—	27	1,162	17,857
Foreign currency translation differences	(176)	(145)	) (142)	_	_	(27)	(490)
Others	1	(211)	)		_	_	(210)
Balance as of March 31, 2021	¥ (44,267)	¥ (46,798)	) ¥ (24,383)	¥ (64)	¥ (128)	¥ (7,179)	¥ (122,819)

### 2. Accumulated depreciation and accumulated impairment losses

#### 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, 2019	¥ 36,873	¥ 7,866	¥ 4,936	¥ 5,025	¥ 1,965	¥ 14,775	¥ 71,440
Balance as of March 31, 2020	31,758	8,209	4,969	4,767	1,894	14,151	65,748
Balance as of March 31, 2021	¥ 31,171	¥ 8,973	¥ 5,091	¥ 4,774	¥ 1,281	¥ 13,676	¥ 64,966

(Note) 1. There is no capitalized borrowing cost for property, plant and equipment for the years ended March 31, 2020 and 2021.

Details of commitment in respect of acquisitions of property, plant and equipment are presented in Note 31. Capital Expenditure Commitments.
 Property, plant and equipment under construction is presented as Construction in progress.

#### (2) Impairment losses

Impairment losses recognized for the year ended March 31, 2020 and 2021 were ¥628 million and ¥128 million, respectively. Impairment loss was recorded in Cost of sales in the Consolidated Statement of Profit or Loss.

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.

Impairment losses recognized for the year ended March 31, 2021 amounting to ¥128 million were recorded in Cost of sales in the Consolidated Statement of Profit or Loss. Impairment losses represented a recognition of impairment losses of construction in progress with the decreased profitability in Japan segment of pharmaceutical business. The recoverable amount is measured based on value in use. However, as the profitability is no longer expected, the total carrying amount is reduced to zero.

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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, 2020	Year ended March 31, 2021	
Beginning balance	¥ 99,348	¥ 173,464	
Acquisition through business combinations (Note)	76,681	—	
Foreign currency translation differences	(2,565)	3,028	
Ending balance	¥ 173,464	¥ 176,492	

(Note) For provisional accounting treatment on business combinations related to Sumitovant Biopharma Ltd. which was acquired through the strategic alliance with Roivant Sciences Ltd.as of March 31, 2020, as the Company finalized the purchase price allocation during the year ended March 31, 2021, acquisition through business combinations for the year ended March 31, 2020 was adjusted retrospectively.

## 2. Accumulated impairment losses

	Millio	Millions of yen			
	Year ended March 31, 2020	Year ended March 31, 2021			
Beginning balance	¥ —	¥ —			
Impairment losses					
Foreign currency translation differences		—			
Ending balance	¥ —	¥ —			

#### 3. Carrying amount

	Millions of yen
Balance as of April 1, 2019	¥ 99,348
Balance as of March 31, 2020	173,464
Balance as of March 31, 2021	¥ 176,492

#### (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. (currently known as Sumitomo Dainippon Pharma Oncology, Inc.) by the Group. The carrying amounts of significant goodwill are as follows:

	Million	Millions of yen		
	As of March 31, 2020	As of March 31, 2021		
Sumitovant Biopharma Ltd. (Note)	¥ 76,075	¥ 77,403		
Sepracor Inc.	68,512	69,708		
Tolero Pharmaceuticals, Inc.	¥ 21,516	¥ 21,892		

(Note) For provisional accounting treatment on business combinations related to Sumitovant Biopharma Ltd. which was acquired through the strategic alliance with Roivant Sciences Ltd.as of March 31, 2020, the Company finalized the purchase price allocation during the year ended March 31, 2021, the amount of goodwill related to Sumitovant Biopharma Ltd. as of March 31, 2020 was adjusted retrospectively.

#### (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, 2020 and 2021 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, 2020	As of March 31, 2021	
¥ 149,643	¥ 152,255	
23,821	24,237	
¥ 173,464	¥ 176,492	
	As of March 31, 2020 ¥ 149,643 23,821	

(Note) For provisional accounting treatment on business combinations related to Sumitovant Biopharma Ltd. which was acquired through the strategic alliance with Roivant Sciences Ltd.as of March 31, 2020, the Company finalized the purchase price allocation during the year ended March 31, 2021, the amount of goodwill related to North America (excluding oncology area) as of March 31, 2020 was adjusted retrospectively.

Impairment losses are recognized when recoverable amount is less than carrying amount, 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 that was measured basis on business plan approved at management meeting. Value in use is determined by the present value of estimated future cash flows based on the past experience and external information, using assumptions such as the planned launch schedules, the probability of success of R&D activities and selling prices of products and developed products.

As the recoverable value of CGU is greater than the carrying amount as a result of the impairment tests as of March 31, 2020 and 2021, 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 13.8% -20.0% and 13.5% -17.0% as of March 31, 2020 and 2021, respectively. Value in use is sufficiently greater than carrying amount of a CGU, and the Group considers that impairment loss is unlikely to occur even if key assumptions used in measuring value in use change within a reasonable range.

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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	Others	Total
Balance as of April 1, 2019	¥ 217,102	¥ 15,954	¥ 248	¥ 233,304
Individual acquisition	3,043	2,661	_	5,704
Acquisitions through business combinations (Note)	289,878	997	—	290,875
Sales and disposals	(3,856)	(2,242)		(6,098)
Foreign currency translation differences	(6,333)	(185)	(2)	(6,520)
Balance as of March 31, 2020	499,834	17,185	246	517,265
Individual acquisition	2,469	2,199	2	4,670
Sales and disposals		(86)	(11)	(97)
Foreign currency translation differences	8,770	212	2	8,984
Others	(7)	58	_	51
Balance as of March 31, 2021	¥ 511,066	¥ 19,568	¥ 239	¥ 530,873

(Note) For provisional accounting treatment on business combinations related to Sumitovant Biopharma Ltd. which was acquired through the strategic alliance with Roivant Sciences Ltd.as of March 31, 2020, as the Company finalized the purchase price allocation during the year ended March 31, 2021, acquisition through business combinations for the year ended March 31, 2020 was adjusted retrospectively.

#### 2. Accumulated amortization and accumulated impairment losses

	Millions of yen			
	Intangible assets related to products	Software	Others	Total
Balance as of April 1, 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)
Amortization	(9,551)	(2,481)	(8)	(12,040)
Impairment losses	(35,592)	_	_	(35,592)
Sales and disposals	_	79	11	90
Foreign currency translation differences	(3,532)	(153)	(1)	(3,686)
Others	_	(3)	_	(3)
Balance as of March 31, 2021	¥ (134,478)	¥ (12,808)	¥ (181)	¥ (147,467)

### 3. Carrying amount

		Millions of yen			
	Intangible assets related to products	Software	Others	Total	
Balance as of April 1, 2019	¥ 165,447	¥ 5,869	¥ 74	¥ 171,390	
Balance as of March 31, 2020	414,031	6,935	63	421,029	
Balance as of March 31, 2021	¥ 376,588	¥ 6,760	¥ 58	¥ 383,406	

(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, 2020 and 2021 were ¥405,492 million, and ¥165,928 million, respectively.

### (2) Significant intangible assets

Significant intangible assets recognized in the Consolidated Statement of Financial Position are as follows:

			Carrying amount	(Millions of yen)	Residual amortization period
			As of March 31, 2020	As of March 31, 2021	As of March 31, 2021
Myovant Sciences Ltd.	relugolix (Note)	In-process research and development	¥ 193,246	¥ 133,184	_
	ORGOVYX®	Patent rights	_	62,335	17 years
Urovant Sciences Ltd.	vibegron (Note)	In-process research and development	89,986	-	-
	<b>GEMTESA<sup>®</sup></b>	Patent rights	_	91,336	15 years
	APL-130277	In-process			
Cynapsus Therapeutics Inc.	(apomorphine hydrochloride)	research and development	54,068	—	-
	KYNMOBI <sup>®</sup>	Patent rights	_	51,328	11 years
Tolero Pharmaceuticals, Inc.	DSP-2033 (alvocidib)	In-process research and development	8,705	_	_
Tolero Pharmaceuticals, Inc.	TP-0903	In-process research and development	16,539	16,828	_
Boston Biomedical, Inc.	BBI608 (napabucasin)	In-process research and development	27,638	_	_

(Note) 1. For provisional accounting treatment on business combinations related to Sumitovant Biopharma Ltd. which was acquired through the strategic alliance with Roivant Sciences Ltd.as of March 31, 2020, as the Company finalized the purchase price allocation during the year ended March 31, 2021, significant intangible assets as of March 31, 2020 was adjusted retrospectively.

2. Myovant is a consolidated subsidiary of the Group and the Group owns approximately 53% of the outstanding shares of Myovant.

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The above table mainly represent the intangible assets related to products arising from the full or partial acquisition of Myovant Sciences Ltd., Urovant Sciences Ltd., Cynapsus Therapeutics Inc. (currently known as Sunovion CNS Development Canada ULC), Tolero Pharmaceuticals, Inc. (currently known as Sumitomo Dainippon Pharma Oncology, Inc.) and Boston Biomedical, Inc. (currently known as Sumitomo Dainippon Pharma Oncology, Inc.) by the Group. The activities of research and development are described in page 32.

As the in-process research and development which is ongoing research development assets are not yet available for use, of which the approval for sales by regulatory authorities has not been obtained, 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. In addition, there exists a risk of inccurring impairment losses due to failure in product commercialization due to the inherent uncertainties in the research and development processes, and due to a decrease in the profitability associated with changes in market environment and other factors.

#### (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 recoverable amount is less than carrying amount, and the carrying amount of intangible assets is reduced to the extent of the recoverable amount. The recoverable amount is determined based on value in use. Value in use is determined by the present value of estimated future cash flows based on the past experience and external information.

The discount rate used in the impairment test for intangible assets is the weighted average cost of capital, etc. set by each cash generating unit. The pre-tax discount rate used in the impairment test of intangible assets were 6.0% - 19.0% and 6.0%-17.0% as of March 31, 2020 and 2021, respectively.

As a result of impairment test, impairment losses amounting to ¥34,568 million were recognized for the year ended March 31, 2020. 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 ¥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) for hematologic malignancies, 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%.

Impairment losses for the year ended March 31, 2021 amounting to ¥35,592 million recognized in selling, general and administrative expenses, and research and development expenses in the Consolidated Statement of Profit or Loss were ¥151 million and ¥35,441 million, respectively.

The impairment losses were mainly impairment loss on in-process research and development of napabucasin (product code: BBI608) amounting to ¥26,952 million yen, which is Global clinical Phase 3 study for colorectal cancer, and impairment loss on in-process research and development of alvocidib (product code: DSP-2033) amounting to ¥8,489 million, which was being developed as a small molecule inhibitor of cyclin-dependent kinase 9 (CDK9) for hematologic malignancies in North America segment

of pharmaceutical business.

As for in-process research and development above, the total carrying amount is reduced due to the discontinuation of their clinical development.

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 contacts. 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	Year ended March 31, 2021	
Depreciation	¥ 3,989	¥ 4,224	
Interest expenses on lease liabilities	261	320	
Expenses related to short-term leases	232	298	
Expenses related to leases of low-value assets	716	790	
Variable lease payments not included in the measurement of lease liabilities	74	48	
Income from sublease of right-of-use assets	646	688	

### (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	Land	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
Additions	2,966	1,165	5	4,136
Sales and disposals	(570)	(1,121)	—	(1,691)
Foreign currency translation differences	212	25	—	237
Others	(68)	_	_	(68)
Balance as of March 31, 2021	¥ 16,221	¥ 4,629	¥ 5	¥ 20,855

(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.

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# 2. Accumulated depreciation and accumulated impairment losses

		Millions of yen			
	Buildings and structures	Machinery and vehicles	Land	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)	
Depreciation	(3,178)	(1,045)	(1)	(4,224)	
Sales and disposals	533	629	—	1,162	
Foreign currency translation differences	(14)	(13)	_	(27)	
Balance as of March 31, 2021	¥ (5,543)	¥ (1,635)	¥ (1)	¥ (7,179)	

(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.

#### 3. Carrying amount

		Millions of yen			
	Buildings and structures	Machinery and vehicles	Land		Total
Balance as of April 1, 2019	¥ 10,862	¥ 3,252	¥		¥ 14,114
Balance as of March 31, 2020	10,797	3,354			14,151
Balance as of March 31, 2021	¥ 10,678	¥ 2,994	¥	4	¥ 13,676

# (3) Lease liabilities

The contractual maturities of lease liabilities are as follows:

	Millions of yen		
	As of March 31, 2020	As of March 31, 2021	
Contractual undiscounted cash flows			
Within 1 year	¥ 6,137	¥ 6,059	
Over 1 year, within 5 years	9,021	9,360	
Over 5 years	3,704	2,307	
Balance of undiscounted lease liabilities	18,862	17,726	
Balance of lease liabilities	17,279	16,861	
Lease liabilities (non-current)	11,493	10,961	
Lease liabilities (current)	5,786	5,900	

## (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	Year ended March 31, 2021	
Repayments of lease liabilities	¥ 4,837	¥ 4,727	
Interest expenses on lease liabilities paid	245	322	
Others	1,022	1,136	
Total	¥ 6,104	¥ 6,185	

# **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, 2020	As of March 31, 2021	
Financial assets at amortized cost			
Loan receivables	¥ 25,923	¥ 27,690	
Others	2,551	2,603	
Financial assets at fair value through profit or loss			
Equity securities, etc.		32	
Financial assets at fair value through other comprehensive incom	ne		
Equity securities, etc.	199,165	190,923	
Bonds	2,001	1,155	
Derivative assets		112	
Total	¥ 229,640	¥ 222,515	
Other financial assets (non-current)	200,923	193,035	
Other financial assets (current)	28,717	29,480	
Total	¥ 229,640	¥ 222,515	

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

1. Details of fair value

The fair values of major investees are as follows:

	Million	s of yen
	As of March 31, 2020	As of March 31, 2021
Roivant Sciences Ltd.	¥ 142,650	¥ 123,110
JCR Pharmaceuticals Co., Ltd.	8,007	12,189
Medipal Holdings Corporation	6,538	6,888
SanBio Company Limited	3,272	5,401
Ono Pharmaceutical Co., Ltd.	4,139	4,812
Suzuken Co., Ltd.	3,637	3,998
Alfresa Holdings Corporation	3,305	3,501
HEALIOS K.K.	2,261	2,504
Mochida Pharmaceutical Co., Ltd.	2,258	2,323
Forest Holdings, Inc.	1,894	1,874
Others	21,204	24,323
Total	¥ 199,165	¥ 190,923

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# 2. Others

The dividend income derived from the financial assets measured at fair value through other comprehensive income held by the Group are ¥1,123 million and ¥942 million for the years ended March 31, 2020 and 2021, 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, 2020 and 2021 are as follows:

	Millions of yen		
	Year ended March 31, 2020	Year ended March 31, 2021	
Fair value at the time of disposal	¥ 1,608	¥ 173	
Accumulated gains (losses)	1,288	42	
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 and ¥28 million for the years ended March 31, 2020 and 2021, respectively.

The accumulated losses (net of tax) of those financial assets measured at fair value through other comprehensive income of which the significant decline in fair value compared with acquisition cost is other-than-temporary, amounting to (¥3,070 million) and (¥38 million) for the years ended March 31, 2020 and 2021, respectively, are reclassified from other components of equity to retained earnings.

#### **19. Inventories**

The details of Inventories are as follows:

	Million	Millions of yen		
	As of March 31, 2020	As of March 31, 2021		
Merchandise and finished goods	¥ 64,683	¥ 76,775		
Work-in-process	2,284	3,982		
Raw materials and supplies	12,401	11,458		
Total	¥ 79,368	¥ 92,215		

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 ¥2,985 million and ¥1,362 million for the years ended March 31, 2020 and 2021, respectively.

# 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, 2020	As of March 31, 2021	
Financial assets measured at amortized cost			
Accounts receivable and notes receivable	¥ 128,478	¥ 127,260	
Other receivables	5,123	7,297	
Contract assets	970	1,310	
Allowance for credit losses	(80)	(1)	
Total	¥ 134,491	¥ 135,866	
Trade and other receivables (non-current)		—	
Trade and other receivables (current)	134,491	135,866	
Total	¥ 134,491	¥ 135,866	

# (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 30. Financial Instruments.

## 21. Cash and Cash Equivalents

The details of cash and cash equivalents are as follows:	Millions of yen	
	As of March 31, 2020	As of March 31, 2021
Financial assets measured at amortized cost		
Cash and deposits	¥ 88,513	¥ 158,520
Short-term investments (cash equivalents)	13,195	35,178
Total	¥ 101,708	¥ 193,698
	+ 101,700	+ 155,050

# 22. Bonds and Borrowings

### (1) Details of Bonds and Borrowings

The details of Bonds and Borrowings are as follows:

		Millions of yen				
	As of March 31, 2020	As of March 31, 2021	Average interest rate	Repayment due date		
Bonds (other than current portion)	¥ —	¥ 118,993	1.47%	September 2050		
Long-term borrowings				June 2022~		
(other than current portion)	25,020	144,866	0.25%	December 2025		
Current portion of long-term borrowings	2,960	4,960	0.16%	—		
Short-term borrowings	270,000	5,000	0.36%	_		
Total	¥ 297,980	¥ 273,819		—		
Bonds and Borrowings (non-current)	25,020	263,859	—	—		
Borrowings(current)	272,960	9,960	_	—		
Total	¥ 297,980	¥ 273,819	—	_		

(Note) The average interest rate is the weighted average interest rate calculated based on the balance of the borrowings as of March 31, 2021.

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2021 and 2020

# (2) Issuance conditions of bonds

A summary of issuance conditions of bonds is as follows:

					Millions of yen		
lssuer	Bond name	Issue date	As of March 31, 2020	As of March 31, 2021	Interest rate (%)	Collateral	Maturity date
Sumitomo Dainippon Pharma Co., Ltd.	1 <sup>st</sup> Unsecured subordinated bonds with interest payment deferrable clause and optional early redemption conditions	September 10, 2020	_	60,000	1.39 (Note 1)	None	September 9, 2050 (Note 3)
Sumitomo Dainippon Pharma Co., Ltd.	2 <sup>nd</sup> Unsecured subordinated bonds with interest payment deferrable clause and optional early redemption conditions	September 10, 2020	_	60,000	1.55 (Note 2)	None	September 9, 2050 (Note 4)
Total	_			120,000			

(Note) 1. The fixed interest rate has been applied since the day after September 10, 2020 and will have been applied until September 10, 2027, and a variable interest rate from the day after September 10, 2027 ("Step-up interest rates" will be applied from the day after September 10, 2027).

The fixed interest rate from the day after September 10, 2027 (Step-up interest rates will be applied from the day after September 10, 2027).
 The fixed interest rate has been applied since the day after September 10, 2020 and will have been applied until September 10, 2030, and a variable interest rate from the day after September 10, 2030 ("Step-up interest rates" will be applied from the day after September 10, 2030).

3. The Company may redeem the Hybrid Bonds at its discretion on each interest payment date from and including September 10, 2027, or in case a tax event or an equity credit change event occurs.

4. The Company may redeem the Hybrid Bonds at its discretion on each interest payment date from and including September 10, 2030, or in case a tax event or an equity credit change event occurs.

The above bonds are classified as financial liabilities measured at amortized cost and measured at cost less direct transaction cost.

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

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

_		Mill	ions of yen		
	Short-term borrowings	Long-term borrowings	Bonds	Lease liabilities	Total
Balance as of April 1, 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
Cash flows provided by financing activities	(265,000)	122,040	118,927	(4,727)	(28,760)
Other changes					
Additions due to acquisition of right-of-use assets				4,089	4,089
Interest expenses	813	213	1,043	320	2,389
Payment of interests	(811)	(213)	(883)	(322)	(2,229)
Effect of foreign currency translation differences	(5)			164	159
Others		(194)		56	(138)
Balance as of March 31, 2021	¥ 5,001	¥ 149,826	¥ 119,087	¥ 16,875	¥ 290,789

(Note) Interest payables are included in the above.

# 23. Trade and Other Payables

The details of trade and other payables are as follows:

	Millions of yen		
	As of March 31, 2020	As of March 31, 2021	
Financial liabilities measured at amortized cost			
Accounts payable and notes payables	¥ 25,640	¥ 26,076	
Other payables	36,611	38,562	
Total	¥ 62,251	¥ 64,638	
Trade and other payables (non-current)	_	—	
Trade and other payables (current)	62,251	64,638	
Total	¥ 62,251	¥ 64,638	

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2021 and 2020

# 24. Other Financial Liabilities

The details of other financial liabilities are as follows:

	Million	s of yen
	As of March 31, 2020	As of March 31, 2021
Financial liabilities at amortized cost		
Deposit received	¥ 3,906	¥ 3,566
Others (Note)	2,754	15,410
Financial liabilities at fair value through profit or loss		
Contingent considerations	31,228	8,337
Others	—	571
Financial liabilities at fair value through other comprehensive ind	come	
Derivative liabilities	45	—
Lease liabilities	17,279	16,861
Total	¥ 55,212	¥ 44,745
Other financial liabilities (non-current)	41,306	21,404
Other financial liabilities (current)	13,906	23,341
Total	¥ 55,212	¥ 44,745

(Note) "Others" under Financial liabilities at amortized cost include upfront payment received from Pfizer, Inc. based on development and commercialization agreement with Myovant Sciences Ltd. on relugolix in North America in oncology and women's health in the year ended March 31, 2021. The details are presented in Note 35. Joint Development and Joint Sales.

# 25. Provisions

# (1) Movements of provisions

The movement of provisions is as follows: Year ended March 31, 2021

Year ended March 31, 2021	Millions of yen		
	Reserve for sales returns	Reserve for sales rebates	Total
Balance at the beginning of the year	¥ 9,120	¥ 75,524	¥ 84,644
Increase	2,410	89,449	91,859
Decrease (utilization)	(2,520)	(75,516)	(78,036)
Decrease (reversal)	(531)	(147)	(678)
Foreign currency translation differences	131	1,931	2,062
Balance at the end of the year	8,610	91,241	99,851
Provision (non-current)	_	_	_
Provision (current)	8,610	91,241	99,851
Total	¥ 8,610	¥ 91,241	¥ 99,851

### (2) Details of Provisions

Provisions are measured based on the best estimation on the timing of settlement of the future obligations as well as cash flows estimated to be required to settle obligations 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 all the products and goods. Among the balance as of March 31 2021, ¥8,598 million was reserve for sales returns recognized for products sold by Sumitomo Dainippon Pharma America, Inc. (hereinafter, SDPA). The future outflow of economic benefits is expected to be incurred within the normal operating cycle from the end of each reporting period.

2. Reserve 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. Among the balance as of March 31, 2021, ¥90,762 million was reserve for sales rebates recognized for products sold by SDPA. Sales rebates related to various insurance programs (Medicaid, etc.) that are applied to major products sold in the United States need time to be determined as the settlement period is about one year. As for estimation of reserves for sales rebates, final distribution channels and applicable insurance programs need to be estimated as the rates of sales rebates, which are the basis of calculation of sales rebates, differ depending on distribution channels (wholesalers, pharmacies and hospitals) and applicable insurance programs. These management judgements would affect estimation of reserves for sales rebates. The future outflow of economic benefits is expected to be incurred within the normal operating cycle from the end of each reporting period.

# 26. Other liabilities

The details of other non-current liabilities and other current liabilities are as follows:

	Million	s of yen
	As of March 31, 2020	As of March 31, 2021
Unearned revenue (Note)	¥ —	¥ 53,281
Accrued bonuses	21,713	28,448
Accrued expenses	8,477	9,204
Others	17,122	17,959
Total	¥ 47,312	¥ 108,892
Other non-current liabilities	7,212	53,046
Other current liabilities	40,100	55,846
Total	¥ 47,312	¥ 108,892

(Note) "Unearned revenue" is upfront payment received from Pfizer, Inc. based on development and commercialization agreement with Myovant Sciences Ltd. on relugolix in North America in oncology and women's health. The details are presented in Note 35. Joint Development and Joint Sales.

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# 27. 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, 2020	As of March 31, 2021
Present value of defined benefit obligations	¥ 99,931	¥ 99,327
Fair value of the plan assets (including retirement benefit trusts)	76,061	84,258
Net defined benefit (assets) liabilities	23,870	15,069
Retirement benefit liabilities	23,870	15,069
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, 2020	Year ended March 31, 2021
Balance at beginning of the year	¥ 102,007	¥ 99,931
Current service cost	3,444	3,057
Interest expense	599	628
Remeasurement of net defined benefit liability (asset)		
Changes in demographic assumptions	(529)	(68)
Changes in financial assumptions	1,362	(934)
Experience adjustments	(2,591)	212
Past service cost	—	27
Benefits paid	(4,933)	(3,566)
Foreign currency translation differences	(12)	15
Others	584	25
Balance at end of the year	¥ 99,931	¥ 99,327

(Note) The weighted average number of payment years of defined benefit obligations are 16.2 years and 14.2 years as of March 31, 2020 and 2021, respectively.

### 3. Plan assets

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

	Million	s of yen
	Year ended March 31, 2020	Year ended March 31, 2021
Balance at beginning of the year	¥ 78,394	¥ 76,061
Interest income	506	371
Benefits paid	(3,505)	(2,856)
Contributions by the employer	2,356	2,365
Remeasurement of defined benefit plans		
Return on plan assets	(1,690)	8,316
Others		1
Balance at end of the year	¥ 76,061	¥ 84,258

(Note) The Group is expected to pay contributions amounting to ¥2,365 million in the year ending March 31, 2022.

### 4. Components of plan assets

The details of plan assets by category are as follows:

	Millions of yen					
	As of March 31, 2020			A	s of March 31, 2021	l i
	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	¥ 10,863	¥ —	¥ 10,863	¥ 22,002	¥ —	¥ 22,002
Debt securities	37,002		37,002	32,419		32,419
General accounts of life insurance companies		8,965	8,965		9,084	9,084
Cash and cash equivalents	5,082		5,082	3,120	—	3,120
Others	_	14,149	14,149		17,633	17,633
Total	¥ 52,947	¥ 23,114	¥ 76,061	¥ 57,541	¥ 26,717	¥ 84,258

(Note) The retirement benefit trusts set for defined benefit pension plans consist of 6.2% and 7.6% in the total plan assets as of March 31, 2020 and 2021 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, 2020	As of March 31, 2021
Discount rate (%)	0.6	0.7

## 6. Sensitivity analysis

The effects of changes in the significant actuarial assumptions on the defined benefit obligations as of March 31, 2020 and 2021 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.

	Million	s of yen
	As of March 31, 2020	As of March 31, 2021
In case that the discount rate increases by 0.5%	¥ (6,877)	¥ (6,615)
In case that the discount rate decreases by 0.5%	¥ 7,217	¥ 7,419

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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 ¥2,473 million and ¥2,734 million for the years ended March 31, 2020 and 2021, respectively.

#### (4) Other Employee benefit expenses

The employee benefit expenses for the years ended March 31, 2020 and 2021 are as follows:

	Million	s of yen
	Year ended March 31, 2020	Year ended March 31, 2021
Salaries	¥ 70,150	¥ 79,251
Bonuses	21,748	30,679
Retirement benefit expenses	7,050	7,268
Others	13,121	14,241
Total	¥ 112,069	¥ 131,439

#### 28. Share-based payments

Myovant Sciences Ltd., the Company's consolidated subsidiary, has 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. has 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. for the years ended March 31, 2020, and 2021 are as follows:

(i) Year ended March 31, 2020

	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.

(ii) Year ended March 31, 2021

	Number of stock options (shares)	Weighted average exercise price (USD)	Weighted average remaining contractual years (year)
Outstanding balance as of April 1, 2020	7,723,302	\$ 9.25	8.08
Granted	1,985,765	\$10.88	_
Exercised	(905,776)	\$ 7.41	_
Expired	(509,960)	\$ 8.32	_
Outstanding balance as of March 31, 2021	8,293,331	\$ 9.90	6.48
Exercisable balance as of March 31, 2021	5,219,403	\$ 9.77	5.26

(Note) 1. The weighted average share price at the time of exercising is \$20.82.

2. The range of exercise prices for outstanding as of March 31, 2021 is from \$2.38 to \$26.17.

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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 and 2021, the assumptions used for the Black-Scholes model are as follows. Also, expected weighted average fair value per one stock option is \$7.22.

	Year ended March 31, 2020	Year ended March 31, 2021
Expected weighted average share price	\$ 11.42	\$18.82
Expected exercise price	\$ 10.63	\$10.88
Expected volatility	73.0%	75.7%
Expected stock option period	6.2 years	6.2 years
Expected dividends		_
Risk-free interest rate	1.2%	0.5%

(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.

#### 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, 2020	Year ended March 31, 2021	
Selling, general and administrative expenses	¥ 984	¥ 7,338	
Research and development expenses	295	2,299	
Total	¥ 1,279	¥ 9,637	

### 29. Share Capital and Other Equity Items

### (1) Share capital

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

	Thousand	s of shares
	Year ended March 31, 2020	Year ended March 31, 2021
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, 2020	Year ended March 31, 2021	
Balance at the beginning of the year	603	605	
Changes during the year	2	1	
Balance at the end of the year	605	606	

(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.

- 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.

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### (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, 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

(ii) For the year ended March 31, 2021

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
Meeting of the Board of directors (October 28, 2020)	Ordinary share	¥ 5,562	¥ 14.00	September 30, 2020	December 1, 2020

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, 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

(ii) For the year ended March 31, 2021

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 24, 2021)	Ordinary share	¥ 5,562	¥ 14.00	March 31, 2021	June 25, 2021

# **30. Financial Instruments**

#### (1) Capital management

In order to achieve sustainable and integrative increase of corporate value and shareholder value, the Group conducts capital management under the policy of introducing merchandise and developed products and making investments in domestic business, North America business, and new business, etc., and also positioning return on profits to shareholders as a key management priority. There are no significant capital restrictions applicable to the Group.

#### (2) Overview of financial risk management

Risk management policy

In order to reduce financial risks (such as credit risk, liquidity risk, and market risks, etc.) arising from business operations, the Group performs risk management. Derivatives are used to mitigate part of such risks and are not used for speculative purposes.

#### (3) Credit risk

1. Summary

Credit risk is the risk of financial loss to the Group if a customer or a counterparty of financial instrument fails to meet its contractual obligations. It mainly arises from the debtors, such as trade receivables due from the Group's customers.

As for the customers' credit risk arising from trade receivables and etc., the Group monitors the status of overdue balances, reviews outstanding balances of each customer according to the Group's internal credit management policies and assesses the credibility of major customers on a regular basis in order to reduce credit risks.

#### 2. Maximum credit risk exposures

The maximum exposures related to the credit risk of financial assets held by the Group are the carrying amount of financial assets presented in the Consolidated Statements of Financial Position.

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

#### 3. Changes in allowance for doubtful accounts

An allowance for doubtful accounts is recognized for expected credit losses for trade receivables and other receivables.

(i) Trade receivables

Allowance for doubtful accounts related to trade receivables that do not contain a significant financing component is recognized at the amount equal to the lifetime expected credit loss by similar receivables.

(ii) Other receivables

For assets of which credit risk significantly increases, in principle, an allowance for doubtful accounts is recognized at the amount equal to the 12-month expected credit loss, and calculated by multiplying the carrying amount by the provision rate calculated by considering prospects of future economic conditions, etc. in addition to the historical rate of credit losses of similar assets. For assets of which credit risk is considered significantly increased, and credit-impaired financial assets, the allowance for doubtful accounts is recognized at an amount equal to the lifetime expected credit losses, and is calculated based on the difference between recoverable amount that is individually determined by considering the prospects of future economic conditions, in addition to the financial conditions of counterparty and total carrying amount.

Any financial asset will be treated as credit-impaired financial assets, if there is a request to change terms and conditions for repayment from the debtor, serious financial difficult of the debtor, or commencement of legal liquidation procedures due to bankruptcy and others of the debtor, etc. In addition, if a financial asset is impaired, the impairment loss is recognized in the account of allowance for doubtful accounts rather than deducted directly from the carrying amount of the asset.

Changes in the allowance for doubtful accounts of the Group are not presented, as they are immaterial.

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## (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 balance of financial liabilities of each contractual maturity is as follows: The interest is represented by the amount of estimated payment in future. (i) 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	5 ¥ 297,980	¥ 299,050	¥ 273,973	¥ 5,000	¥ 20,077	¥ —	¥ —	¥ —

(ii) As of March 31, 2021

	Millions of yen								
	Carrying amount	Total contractual cash flow	Due within one year or less	Due after one year within two years	years	fter two s within e years	Due after three years within four years	Due after four years within five years	Due after five years
Borrowings	¥ 154,826	¥ 156,493	¥ 10,333	¥ 20,410	¥	323	¥ 60,289	¥ 65,138	¥ —
Bonds	118,993	134,256	1,764	1,764		1,764	1,764	1,764	125,436
Total	¥ 273,819	¥ 290,749	¥ 12,097	¥ 22,174	¥	2,087	¥ 62,053	¥ 66,902	¥ 125,436

(Note) The principal amount of publicly offered hybrid bonds (publicly offered subordinated bonds) is included in "Due after five years" based on the contractual maturity date, but may be redeemed early due to special provisions. The details are presented in Notes to Consolidated Financial Statements, Note 22. Bonds and Borrowings.

#### (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, 2020	As of March 31, 2021		
Receivables	\$ 1,569,214	\$ 2,171,497		
Payables	92,659	107,801		
Net exposures of the Consolidated Statement of Financial Position	on 1,476,555	2,063,696		
Forward foreign exchange contracts		(119,589)		
Net exposures	\$ 1,476,555	\$ 1,944,107		

Receivables are mainly foreign currency deposit, trade receivables and loan receivables. Payables are mainly trade payables and other payables.

Forward foreign exchange contracts are used for trade receivables recorded with a certain export transactions.

(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 ¥5,577 million and ¥7,477 million as of March 31, 2020 and 2021, 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, 2021. 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 c March 31	-	As c March 31			
	Carrying amount	Fair value	Carrying amount	Fair value		
Financial liabilities measured at amortized cost	¥ —	¥ —	¥ —	¥ —		
Bonds			118,993	122,646		
Borrowings	297,980	297,985	154,826	154,849		
Total	¥ 297,980	¥ 297,985	¥ 273,819	¥ 277,495		

Fair value measurement of main financial instruments at amortized cost are as follows: (i) Bonds

The fair value of bonds is measured at market prices for the same debt in inactive markets at the reporting date. Fair value hierarchy of the bonds is classified as Level 2.

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(ii) Borrowings

The fair value of the borrowings is measured at the present value of remaining principal and interest discounted using an interest rate that would be used for new borrowings. Fair value hierarchy of the borrowings is classified as Level 3.

3. Financial instruments at fair value in the Consolidated Statement of Financial Position The fair value hierarchy of financial instruments at fair value in the Consolidated Statement of Financial Position is as follows:

Transfers of financial instruments among levels of fair value hierarchy are recognized at each year-end. No transfers of significant financial assets and liabilities among levels occurred in the years ended March 31, 2020 and 2021.

	Millions of yen					
	Level 1	Level 2	Level 3	Total		
Financial assets measured 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 measured at fair value						
through profit or loss						
Contingent consideration	—		31,228	31,228		
Financial liabilities measured at fair value						
through other comprehensive income						
Derivative liabilities	—	45		45		
Total	¥ —	¥ 45	¥ 31,228	¥ 31,273		

#### (i) As of March 31, 2020

(ii) As of March 31, 2021

	Millions of yen					
	Level 1		Level 2	Level 3	Т	otal
Financial assets measured at fair value						
through profit or loss						
Investment securities, etc.		32	_	—		32
Financial assets measured at fair value						
through other comprehensive income						
Investment securities, etc.	52,0	48		138,875	1	90,923
Bonds		—	1,155	—		1,155
Derivative assets		—	112	—		112
Total	¥ 52,0	80	¥ 1,267	¥ 138,875	¥ 1	92,222
Financial liabilities measured at fair value						
through profit or loss						
Contingent consideration		—	_	8,337		8,337
Derivative liabilities		_	539	_		539
Others		32				32
Total	¥	32	¥ 539	¥ 8,337	¥	8,908

#### 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, 2020	Year ended March 31, 2021		
Balance at the beginning of the year	¥ 16,942	¥ 155,651		
Purchase	112,090	2,689		
Changes in financial assets measured at fair value				
through other comprehensive income	27,640	(19,180)		
Sales/settlement	(668)	(173)		
Others	(353)	(112)		
Balance at the end of the year	¥ 155,651	¥ 138,875		

#### (ii) Financial liabilities

	Millions of yen		
	Year ended March 31, 2020	Year ended March 31, 2021	
Balance at the beginning of the year	¥ 81,352	¥ 31,228	
Changes in fair value of contingent consideration (Note)	(48,474)	(22,463)	
Foreign currency translation differences	(1,650)	(428)	
Balance at the end of the year	¥ 31,228	¥ 8,337	

(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%-14.2% are applied. The future cash flow used in discounted cash flow method are estimated under many assumptions such as the timing of launch of products under development in unlisted companies, probability of success of research and development activities, and plans such as revenue forecast, etc. These assumptions and discount rates may be affected by uncertain future events. 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 Elevation Pharmaceuticals, Inc. (currently known as Sunovion Respiratory Development Inc., hereinafter "Elevation"), and Tolero Pharmaceuticals, Inc. (currently known as Sumitomo Dainippon Pharma Oncology, Inc., hereinafter "Tolero"), the contingent considerations are

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2021 and 2020

to be additionally paid to former shareholders upon the achievement of predetermined milestone.

As for the acquisition of Elevation, consideration for acquisition amounting to \$189 million (¥17,800 million) has been paid till March 31, 2021, and it is possible to pay a maximum amount of \$210 million (¥23,249 million), before considering time value of money, on achievement of the commercial milestones determined based on revenue earned.

As for the acquisition of Tolero, consideration for acquisition amounting to \$195 million (¥22,165 million) has been paid till March 31, 2021, and it is possible to pay a maximum amount of \$430 million (¥47,605 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 (¥16,607 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 fair value of contingent consideration is measured by taking account of probability of achievement of development milestones of a specific developed product and revenue to be earned since commencement of sales and time value of money. The development milestones in a specific developed product, forecast on future sales, and discount rates and etc may be affected by uncertain future events.

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 is ¥237,206 million (undiscounted) and ¥87,461 million (undiscounted) as of March 31, 2020 and 2021, respectively. The amounts payable by due date of contingent consideration are not presented because of the uncertainty.

Contingent consideration for the acquisition of Boston Biomedical, Inc. (currently known as Sumitomo Dainippon Pharma Oncology, Inc.) are reduced to zero for the year ended March 31, 2021 due to the discontinuation of its clinical development of napabucasin (product code: BBI608) which is Global clinical Phase 3 study for colorectal cancer.

Millions of ven As of As of March 31, 2020 March 31, 2021 ¥ 1,088 Increase by 5% ¥ 111 Revenue (1,088)(111)Decrease by 5% Increase by 0.5% (435)(111)Discount rate Decrease by 0.5% 326 111

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:

### **31. Capital Expenditure Commitments**

Capital expenditure commitments of acquisition of assets are as follows:

	Millions of yen		
	As of March 31, 2020	As of March 31, 2021	
Property, plant and equipment	¥ 2,475	¥ 4,631	
Intangible assets	73,395	71,765	
Total	¥ 75,870	¥ 76,396	

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.

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2021 and 2020

# 32. Subsidiaries and Associates

## (1) The significant subsidiaries and associates

The significant subsidiaries and associates of the Group as of March 31, 2021 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 Shared service for general management operations (North America)	100%
Sunovion Pharmaceuticals Inc.	Marlborough, MA, U.S.	\$0 thousand	Manufacturing and sales of pharmaceuticals (North America)	100%
Sumitomo Dainippon Pharma Oncology, Inc.	Cambridge, MA, 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, manufacturing and sales of pharmaceuticals in the women's health and prostate cancer area (North America)	53.45%
Urovant Sciences Ltd.	London, U.K.	\$1 thousand	R&D in the urology area (North America)	100%
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%

#### (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

	Million	Millions of yen		
	As of March 31, 2020	As of March 31, 2021		
Non-controlling interests ratio	47.9%	46.6%		
Accumulated amount of non-controlling interests	82,716	67,583		

2. Net profit or loss allocated to non-controlling interests and dividends paid to non-controlling interests

	Million	Millions of yen	
	Year ended March 31, 2020	Year ended March 31, 2021	
Net profit or loss allocated to non-controlling interests	¥ (3,514)	¥ (13,141)	
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

	Million	s of yen
	Year ended March 31, 2020	Year ended March 31, 2021
Revenue	¥ —	¥ 6,294
Net profit (loss)	(7,336)	(28,368)
Comprehensive income (loss)	(7,425)	(30,028)

(ii) Summary of Consolidated Statement of Financial Position

	Million	Millions of yen		
	As of March 31, 2020	As of March 31, 2021		
Non-current assets	¥ 195,432	¥ 197,959		
Current assets	9,565	78,011		
Total assets	204,997	275,970		
Non-current liabilities	31,110	106,276		
Current liabilities	10,004	30,943		
Total liabilities	41,114	137,219		
Total equity	163,883	138,751		
Total liabilities and equity	204,997	275,970		

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(iii) Summary of Consolidated Statement of Cash Flows

	Millions of yen	
	Year ended March 31, 2020	Year ended March 31, 2021
Net cash flows from operating activities	¥ (2,090)	¥ 39,327
Net cash flows from investing activities	1,362	(977)
Net cash flows from financing activities	30	25,259
Effect of exchange rate changes on cash and cash equivalents		_
Net increase (decrease) in cash and cash equivalents	(698)	66,515
Cash and cash equivalents at end of year	8,489	75,004

(Note) Net increase (decrease) in cash and cash equivalents includes foreign currency translation differences arising from translating local currencies into Japanese yen for the years ended March 31, 2020, and 2021.

# **33. 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			
Туре	Company name	Description of		ended 31, 2020		ended 31, 2021
	name	transaction	Transaction amount	Outstanding balance	Transaction amount	Outstanding balance
Parent company	Sumitomo Chemical Company, Limited	Lending and collection of funds	¥ (16,520)	¥ 25,881	¥ 879	¥ 27,678

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, 2020	Year ended March 31, 2021
Basic remuneration and bonus	¥ 465	¥ 478

### 34. Business Combinations and Acquisition of Non-Controlling Interests

(Business combinations through acquisition) There were no significant business combinations for the year ended March 31, 2021.

- 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%

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2021 and 2020

- 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, "Roivant") as of December 27, 2019.

In order to achieve sustained 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 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 this 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 the year ended March 31, 2023 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 transferred its ownership of share of full or partial interests of five subsidiaries (Myovant Sciences Ltd. (hereafter "Myovant"), Urovant Sciences Ltd., Enzyvant Therapeutics Ltd., Altavant Sciences Ltd., and Spirovant Sciences Ltd.) to the new company, Sumitovant Biopharma Ltd. (hereafter "Sumitovant") which is established for this alliance, and the Company has acquired all the shares of Sumitovant.

Sumitovant 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
   <u>Consideration transferred Cash 224,555 million yen</u>
   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.

(7) The details of fair value of assets acquired and liabilities assumed, non-controlling interests and goodwill Fair value of the assets acquired, and the liabilities assumed were measured at provisional amount at the end of the previous accounting period. However, during the year ended March 31, 2021, the company finalized the purchase price allocation. Accordingly, as a result of reflecting the new information obtained about facts and circumstances that existed as of the acquisition date, retrospective adjustments to provisional fair value were made as below.

			IVIIIIOIIS OF yell
Account	Provisional fair value	Adjustments	Finalized fair value
Non-current assets			
Intangible assets	¥ 291,643	¥ (768)	¥ 290,875
Others	3,661	_	3,661
Current assets			
Cash and cash equivalents	18,781	—	18,781
Others	6,172	—	6,172
Non-current liabilities	40,840	(100)	40,740
Current liabilities	19,307	—	19,307
Net assets	260,110	(668)	259,442
Non-controlling interests (Note 2)	107,783	3,785	111,568
Goodwill (Note 3)	72,228	4,453	76,681

(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.

As a result of the completion of purchase price allocation, the Consolidated Statement of Comprehensive Income for the year ended March 31, 2020, the Consolidated Statement of Financial Position as of March 31, 2020, and the Consolidated Statement of Changes in Equity for the year ended March 31, 2020 were retrospectively adjusted.

(8) Cash outflows arising from acquisition of subsidiaries

	Millions of yen
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

Millions of ven

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2021 and 2020

- (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 (¥16,712 million)

Net profit (loss)

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 to strengthen the relationship between the Group and Myovant additionally after the acquisition of all the shares of Myovant held by Sumitovant for the year ended March 31, 2020. As a result, capital surplus was increased by ¥1,616 million.

The Group acquired an additional 2.1% of the shares of Myovant to strengthen the relationship between the Group and Myovant for the year ended March 31, 2021. As a result, capital surplus was increased by ¥919 million. To provide Urovant Sciences Ltd. optimal support in maximizing the value of vibegron, the Group acquired all of the shares of Urovant Sciences Ltd., which then became a wholly owned subsidiary of the Group. As a result, capital surplus was decreased by ¥2,248 million. Transaction costs incurred from Urovant Sciences Ltd. becoming a wholly owned subsidiary was ¥494 million, which is deducted from capital surplus.

### **35. Joint Development and Joint Sales**

The Group has entered into a development and commercialization agreement related to the Group's developed products and finished goods with its alliance partner.

On December 26, 2020, Myovant, which is a subsidiary of the Company, and Pfizer Inc. entered into a development and commercialization agreement on relugolix in oncology and women's health in the U.S. and Canada.

Based on this agreement, Myovant recognizes sales revenue of relugolix monotherapy tablet and relugolix combination tablet (hereinafter, "combination tablet"), and Myovant and Pfizer Inc. will equally share profits and certain expenses necessary for development and sales.

Myovant received \$650 million (¥67,353 million) from Pfizer Inc.as upfront payment. Also, Myovant will receive at a maximum of \$4,200 million (¥464,982 million), including \$200 million (¥22,142 million) in potential regulatory milestones for U.S. Food and Drug Administration approvals for relugolix combination tablet in women's health, and tiered sales milestones upon reaching certain thresholds up to \$2,500 million in net sales for prostate cancer and also for women's uterine fibroids and endometriosis. If Pfizer Inc. exercises the option to commercialize relugolix in oncology outside of the U.S. and Canada, excluding certain Asian countries, Myovant will receive \$50 million (¥5,536 million) and royalties on sales as well.

After this alliance, the Group recognizes sales revenue and cost of sales related to the sale of relugolix by Myovant. In addition to selling, general and administrative expenses, and research and development expenses of Myovant related to relugolix incurred in the Group, the Group recognizes expenses paid to Pfizer Inc. by Myovant for equally sharing profits in cost of sales, selling, general and administrative expenses, and research and development expenses according to the nature as well.

Based on the agreement, the Group (via Myovant) received \$650 million (¥67,353 million) as upfront payment from Pfizer Inc. for the year ended March 31, 2021. The Group recognized \$504 million (¥52,224 million) of this payment as other liabilities and subsequently recognizes as revenue for

consideration related to joint development in six years. Also, the Group recognized \$146 million (¥15,129 million) of this payment as redemption of research and development expenses afforded by the Group in other financial liabilities. The Group derecognizes the other financial liabilities whenever research and development expenses related to relugolix afforded by the Group is incurred by Myovant.

#### **36. 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 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, 2021, and notes, comprising 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, 2021, 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.

# **Key Audit Matters**

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the consolidated financial statements of the current period. These matters were addressed in the context of our audit of the consolidated financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

oncology area in North America			
The key audit matter	How the matter was addressed in our audit		
As described in Note 15. "Goodwill" to the consolidated financial statements, Sumitomo Dainippon Pharma Co., Ltd. and its subsidiaries (hereinafter, collectively referred to as the "Group") recognized goodwill of ¥24,237 million in the consolidated statement of financial position, which was allocated to the oncology area, a cash generating unit included within the North America segment of the pharmaceutical business (hereinafter, the "oncology area in North America"). The goodwill, representing 1.8% of the total assets in the consolidated financial statements, arose when the Group acquired control of Boston Biomedical, Inc.	In order to assess whether the estimate of the recoverable amount used for the impairment testing on goodwill allocated to the oncology area in North America was reasonable, we requested the component auditors of Sumitomo Dainippon Pharma America, Inc. (hereinafter, "SDPA"), a consolidated subsidiary that oversees the oncology area in North America, to perform an audit. We evaluated the report of the component auditors and concluded on whether sufficient and appropriate audit evidence was obtained from the following procedures, among others:		
and Tolero Pharmaceuticals, Inc.	(1) Internal control testing Testing the design and operating effectiveness of certain		
The Group presents its consolidated financial statements in accordance with International Financial Reporting	internal controls relevant to measuring the value in use used for the impairment testing on goodwill allocated to the		

oncology area in North America with a particular focus

Reasonableness of the estimate of the recoverable amount used for the impairment testing on goodwill allocated to the

Standards (IFRS). Goodwill is tested for impairment annually

or whenever there is an impairment indicator. In the impairment testing, when the recoverable amount is less than the carrying amount, the carrying amount is reduced to the recoverable amount, and the resulting decrease in the carrying amount is recognized as an impairment loss.

In the current fiscal year, the Group used the value in use as the recoverable amount in the impairment testing on goodwill allocated to the oncology area in North America. The future cash flows used for measuring the value in use were estimated based on the business plan of the oncology area in North America prepared by management. Key assumptions underlying the projected revenue from new medicines currently being developed in the oncology area in North America, such as the planned launch schedules, the probability of success of R&D activities and selling prices, among others, involved a high degree of estimation uncertainty. Accordingly, management judgement thereon had a significant effect on the estimated future cash flows. Moreover, selecting the appropriate calculation method and input data for estimating the discount rate used to measure the value in use required a high degree of expertise in valuation.

We, therefore, determined that the reasonableness of the estimate of the recoverable amount used for the impairment testing on goodwill allocated to the oncology area in North America was one of the most significant in our audit of the consolidated financial statements for the current fiscal year, and accordingly, a key audit matter.

on controls relevant to estimating the future cash flows. (2) Assessment of the reasonableness of the estimated value in use

Inquiry of management and the personnel responsible for the oncology area in North America about the rationale for key assumptions adopted in developing the business plan of the oncology area in North America that formed the basis for the estimated future cash flows; in addition to the assessment of the reasonableness of the estimated value in use by performing the following procedures:

- compared the business plan that formed the basis for estimating the future cash flows with the business plan approved by management, for consistency;
- compared key assumptions underlying the projected revenue from new medicines currently being developed, such as the planned launch schedules, the probability of success of R&D activities, and selling prices, with information obtained from external professional research organizations;
- compared key assumptions used for accounting estimates in the current fiscal year with those in the previous fiscal year to examine whether the reasons for changes in assumptions made during the current fiscal year were reasonable in view of the current year circumstances; and
- involved valuation specialists who assisted in the assessment of the reasonableness of the discount rate by comparing it with a rate independently estimated by the specialists using external information.

Sumitomo Dainippon Pharma America, Inc. within the North America segment of the pharmaceutical business			
The key audit matter	How the matter was addressed in our audit		
In the consolidated statement of financial position for the current fiscal year, the Group recognized reserves for sales rebates of ¥90,762 million related to SDPA, a consolidated subsidiary within the North America segment of the pharmaceutical business, which represented 6.9% of the total assets.	In order to assess the reasonableness of the estimate of reserves for sales rebates under the Medicaid program that cover major products of SDPA within the North America segment of the pharmaceutical business, we requested the component auditors of SDPA to perform an audit and evaluated the report of the component auditors and concluded on whether sufficient and appropriate audit		
As described in Note 25. "Provisions" to the consolidated financial statements, the Group recognizes reserves for sales rebates at an estimated amount to be paid for sales	evidence was obtained from the following procedures among others:		
rebates related to public programs, and wholesale and other contracts.	<ol> <li>Internal control testing Testing the design and operating effectiveness of certain internal controls relevant to calculating reserves for sales</li> </ol>		
Sales rebates related to various insurance programs (including Medicaid) that cover major products sold in the	rebates related to insurance programs including Medicaid for the major products of SDPA.		

# Reasonableness of the estimate of reserves for sale rebates under the Medicaid program that cover major products of

# **Independent Auditor's Report**

U.S. are material revenue adjustment items in terms of amount. As the length of time until the settlement can be as long as one year, it takes a long time period to fix the amount. In addition, the rebate rates used as the basis for calculating sales rebates differ depending on distribution channel (wholesalers, pharmacies, and hospitals) and insurance programs. To estimate reserves for sales rebates, the ultimate distribution channel and the insurance program to be applied are required to be estimated. Accordingly, management judgment thereon had a significant effect on the estimate of reserves for sales rebates.

We, therefore, determined that the reasonableness of the estimate of reserves for sales rebates under the Medicaid program that cover major products of SDPA within the North America segment of the pharmaceutical business was one of the most significant in our audit of the consolidated financial statements for the current fiscal year, and accordingly, a key audit matter.

- (2) Assessment of the reasonableness of the estimate of reserves for sales rebates under the Medicaid program that cover major products of SDPA Assessment of the reasonableness of the estimate of reserves for sales rebates by performing the following procedures:
  - assessed the accuracy of the estimate by comparing the reserves for sales rebates recognized in the past years with actual amounts paid;
  - assessed the reasonableness of the estimated quantity of units sold within each distribution channel for each major product considering external information provided by wholesalers and others; and
  - involved government pricing specialists who assisted in examining whether the method of calculating sales rebate rates was based on the programs effective at the time of estimation.

# 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 with regard to 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.

From the matters communicated with corporate auditors and the board of corporate auditors, we determine those matters that were of most significance in the audit of the consolidated financial statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

### 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 Hiroyuki Matano Designated Engagement Partner Certified Public Accountant Masato Tateishi

Designated Engagement Partner Certified Public Accountant

# KPMG AZSA LLC

Osaka Office, Japan June 24, 2021

# **Value Chain Initiatives**

#### 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.

## **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<sup>\*1</sup> 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.



# **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.

→ Please see the corporate website for more details. Corporate Regulatory Compliance & Quality Assurance: https://www.ds-pharma.com/csr/patients\_medical\_ personnel/reliability\_assurance.html Supply Chain: https://www.ds-pharma.com/csr/supply\_ chain/



Research

Development

Obtaining Approval

**Production and Quality Control** 

Corporate Regulatory Compliance & Quality Assurance / Medical Science

M&A and Alliance

**Contribution to Societies / Environment** 

# 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.

- $\bullet$  We have established a quality assurance system that delivers global "A-N-SHI-N\*3."
- 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 patients, their families, and healthcare professionals.
- We produce materials for the proper use of pharmaceutical products, support the provision of information by medical representatives (MRs), and review externally-directed information and materials.

→ Please see the corporate website for more details. Corporate Regulatory Compliance & Quality Assurance: https://www.ds-pharma.com/ csr/patients\_medical\_personnel/reliability\_assurance.html

# 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
- 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.

### **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.



Sales and Marketing

Cashpoint\*2

Patients

Health Insurance Pharmacies

**Medical Institutions** 

# **Contribution to Societies**

Sumitomo Dainippon Pharma is working on offering solutions to problems in society, by listening to expectations and requests, and reflecting them in our business operations and social contribution activities.

- We promote R&D activities through industry-academia collaboration in infectious diseases and vaccines such as malaria.
- We support the development of healthcare infrastructure in developing countries such as educating healthcare professionals.
- We strive to improve the disease-related awareness of patients, their families, and society.
- We implement community contribution activities such as activities to support the development of the next generation, and social contributions and donations.

### **Environment**

Sumitomo Dainippon Pharma is aware of its responsibility for its own environmental impact and is working to reduce environmental impact across all business activities.

Wholesalers

- We implement initiatives to reduce our greenhouse gas (GHG) emissions to contribute to the building of a low-carbon society.
- We work to effectively use water resources and reduce waste.
- We promote dialogue with stakeholders with the proactive disclosure of environmental information.
- We implement forest conservation activities contributing to the preservation of biodiversity.
- \*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 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. Please see page 171 for details of basic knowledge of pharmaceuticals.
- \*3 A-N-SHI-N: Trustworthiness, reliability, peace of mind, making people feel reassured and safe.

# 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.

# **Basic Knowledge of Pharmaceuticals**

#### What are pharmaceuticals?

Pharmaceuticals are used to diagnose, treat or prevent illness in a form that matches each purpose, such as internal use, external use, and injection. There are three types of pharmaceuticals: "prescription pharmaceuticals" and "over-the-counter (OTC) pharmaceuticals," which can be purchased at pharmacies, drug stores, and online, and "pharmaceuticals requiring guidance" that must be sold in person to the user.

Sumitomo Dainippon Pharma researches and develops, manufactures and sells prescription pharmaceuticals called "new drugs (brand-name drugs)," which are usually created over a period of 10 or more years and substantial R&D investment. To provide effective and safe drugs, numerous regulations have been established, from research and development to launch, and pharmaceutical companies are required to verify their quality, efficacy and safety for a certain post-marketing period of time (reexamination period). Please see page 169 for details about our value chain initiatives.

#### Research and development and approval of new drugs

The efficacy and safety of new drugs are studied through the process of basic research, non-clinical studies, and clinical studies. Subsequently, after approval by the Minister of Health, Labor and Welfare and the listing of "drug price standard," the drug is covered by National Health Insurance (NHI) and can be prescribed to patients. The approval system varies by country, and the materials that each country's system requires must be submitted.

New drugs created through drug discovery are useful not only to treat and prevent disease, but also to promote cutting-edge research in various fields including medicine and pharmacology through drug discovery activities, leading to the development of science.

#### Pharmaceuticals and intellectual property

Research and development of a new drug takes a long time, and the probability of successfully launching a new drug is extremely low at 1 out of 22,407 possible outcomes. Furthermore, enormous R&D expenses are required (please see the ratio of R&D expenses to revenue of the Company on page 9).

Without the proper protection of the intellectual property of the developed drug, pharmaceutical companies will have a difficult time continuing to research and develop new drugs. Therefore, since pharmaceutical companies have the exclusive right of manufacturing and marketing new drugs for a certain period of time, they acquire and protect their intellectual property, mainly the patent rights.

A patent right is the right to protect an invention and is valid for 20 years from the patent's filing date. Pharmaceuticals require approval for manufacturing and marketing based on the Act on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices, and because it takes a long time to obtain that approval, the patent period will be eroded, so in some cases, an extension of the patent's life of up to five years may be permitted.

Pharmaceutical-related patents include "substance patents" that exclusively protect the pharmaceutical itself with a patent for the substance, and "method of use patents" related to new efficacies and effects and the safety of specific substances. There are also "formulation patents" that are granted to new formulation innovations such as drug stabilization, and "process patents" that are granted if the process of production is different even for the exact same drug.

#### Generic name and product name

Pharmaceuticals have generic names and product names. The generic name is the "ingredient name" that indicates the active ingredient of the drug itself, while the product name is the "brand name" registered as a trademark by the pharmaceutical company. Even if the product name is different, when the drug has the same active ingredient, the generic name is the same and is universally used.

#### **Generic drug**

When the reexamination period for verifying the efficacy and safety of a new drug and the term of its patent right have both expired, other pharmaceutical companies will be able to manufacture and sell drugs containing the same active ingredient as the new drugs (brand-name drugs).

Drugs that contain the same active ingredient as the new drug are called generic drugs after the generic name, which is the ingredient name.

#### **Drug price system**

In Japan, under the universal health insurance system, prescription pharmaceuticals must not only obtain approval for their manufacture and marketing, but must also be listed in the "drug price standard." The "drug price standard" establishes the "product name" and "price" of pharmaceuticals that can be used for treatments that are covered by NHI, and is the official drug price set by the Minister of Health, Labor and Welfare.

In the United States, since there is no universal public health insurance that covers all citizens, the market is characterized by the extremely large presence of private health insurance companies. Moreover, based on market principles in operation between pharmaceutical companies, insurance companies and medical institutions, pharmaceutical companies can independently set drug prices.

Drug prices in Japan tend to be lower than in the United States and other countries which uses a free price system.

#### National Health Insurance (NHI) drug price revision

The drug price standard in Japan is based on the premise that the actual purchase price reflects the official price of prescription pharmaceuticals.

The Ministry of Health, Labor and Welfare reviews drug prices (drug price revisions) generally once every two years to ensure that market transaction prices are reflected in drug prices. In addition, in the year between the biannual drug price revisions, an "interim year revision" is supposed to be applied to products that substantially deviate from the drug price based on the idea that the actual market price will be reflected in the drug price in a timely manner so as to lower the financial burden on the public.

(Note) The Company has revised basic knowledge of pharmaceuticals based on "Textbook 2020-2021" published by the Japan Pharmaceutical Manufacturers Association.

#### Glossary

An explanation of terms used in the pharmaceutical industry.

#### Best in class

New drugs that have a clear advantage over the existing drugs.

#### Blockbuster

A new drug with unprecedented efficacy, such as a product that generates profits that far exceed development costs. While having no clear definition in terms of sales, it often refers to products that achieve more than ¥100 billion or \$1 billion annually in sales.

#### First in class

Highly innovative pharmaceuticals. Notably, it is an original drug that is highly novel and effective and can substantially transform the conventional system of treatment.

#### In-licensing

Acquisition of the right to sell or develop a drug or drug candidate compound from another company. Typically, a portion of the profit is continuously paid to the licensor, and the profit is less than that of products developed in-house.

#### Modality

This refers to the material classification (category) of a drug, and specifically includes small molecule compounds, therapeutic antibodies, nucleic acid drugs, regenerative medicine and cell therapy, and gene therapy. The definition of modality tends to shift from "substance" to "means," and therapeutic applications other than pharmaceuticals can be called a modality.

#### MR

Abbreviation for Medical Representative. Their main task is to collect, provide, and communicate information on the quality, efficacy, and safety of pharmaceuticals to healthcare professionals such as doctors and pharmacists to ensure their proper use and dissemination.

#### NDA

Abbreviation for New Drug Application, and refers to new drug applications in the United States.

#### Pipeline

A compound that is a new drug candidate.

#### POC

Abbreviation for Proof of Concept, which is the confirmation of expected safety and efficacy in humans.

#### **Precision Medicine**

High-precision healthcare through the understanding of pathophysiology and pathogenesis based on the latest science and technology, the stratification of patients using biomarkers, and the predication of therapeutic effects.

#### QOL

Abbreviation for Quality of Life.

#### Unmet medical needs

Medical needs that have not yet been met, in other words, medical needs for which there are still no effective treatment.

# Corporate Profile (As of June 30, 2021)

Name	Sumitomo Dainippon Pharma Co., Ltd.	Ordinary general	June		
Establishment	May 14, 1897	meeting of shareholders			
Date of merger	October 1, 2005	Main banks	Sumitomo Mitsui Banking Corporation Sumitomo Mitsui Trust Bank, Limited MUFG Bank, Ltd.		
Representative	Hiroshi Nomura, Representative Director, President and CEO				
Number of employees	3,109 (7,032: consolidated)	Key facilities	Osaka Head Office (Osaka) Tokyo Head Office (Tokyo) 13 Branches, 2 Plants (Mie, Oita), 2 Research Laboratories (Osaka), 2 Distribution Centers (Hyogo, Saitama)		
Osaka head office	6-8, Doshomachi 2-chome, Chuo-ku, Osaka 541-0045, Japan TEL: +81-6-6203-5321 FAX: +81-6-6202-6028				
Tokyo head office	13-1, Kyobashi 1-chome, Chuo-ku, Tokyo 104-8356, Japan TEL: +81-3-5159-2500 FAX: +81-3-5159-2945	Businesses (Consolidated)	<ol> <li>Manufacturing and sales of pharmaceuticals</li> <li>Related businesses</li> <li>(Manufacturing and sales of food ingredients, food additives, veterinary</li> </ol>		
Capital	¥22.4 billion				
Total number	397,900,154		medicines, and others)		
of shares issued Stock exchange listing	Tokyo Stock Exchange	Composition of revenue (Consolidated:	Others Pharmaceuticals 92.8%		
Securities code	4506	Fiscal year ended March 31, 2021)	¥516.0 billion		
Fiscal year-end	March 31				

#### Major consolidated subsidiaries (Japan)

	Establishment	Ownership	Fiscal year-end	Number of employees	Businesses
DSP GOKYO FOOD & CHEMICAL Co., Ltd.	Oct 1947	100%	March 31	208	Manufacturing and sales of food ingredients, food additives, chemical product materials, etc.
DS Pharma Animal Health Co., Ltd.	Jul 2010	100%	March 31	98	Manufacturing, and sales of veterinary medicines, etc.
DS Pharma Promo Co., Ltd.	Jun 1998	100%	March 31	42	Manufacturing and sales of pharmaceuticals, etc.

### Major consolidated subsidiaries (Overseas)

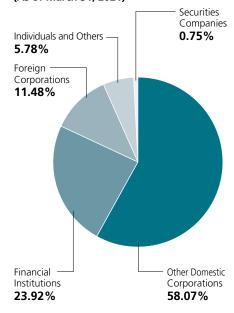
	Establishment	Ownership	Fiscal year-end	Number of employees	Businesses
Sumitomo Dainippon Pharma America, Inc.	Jul 2009	100%	March 31	166	Holding company, shared service for general management operations
Sunovion Pharmaceuticals Inc.	Jan 1984	100%	March 31	1,251*	Manufacturing and sales of pharmaceuticals
Sumitomo Dainippon Pharma Oncology, Inc.	Nov 2006	100%	March 31	193	R&D in the oncology area
Sumitovant Biopharma, Inc.	Oct 2019	100%	March 31	79	Implement oversight of Sumitovant group companies and formulation of potential business strategies for consideration of its group companies
Myovant Sciences Ltd.	Feb 2016	53%	March 31	538*	R&D, manufacturing and sales of pharmaceuticals in the women's health, prostate cancer area
Urovant Sciences Ltd.	Jan 2016	100%	March 31	290*	R&D, manufacturing and sales of pharmaceuticals in the urology area
Enzyvant Therapeutics Ltd.	Jan 2016	100%	March 31	26*	R&D in the pediatric rare diseases area
Altavant Sciences Ltd.	Sep 2017	100%	March 31	21*	R&D in the respiratory rare diseases area
Spirovant Sciences Ltd.	Feb 2019	100%	March 31	25*	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

\* Include employees of consolidated subsidiaries

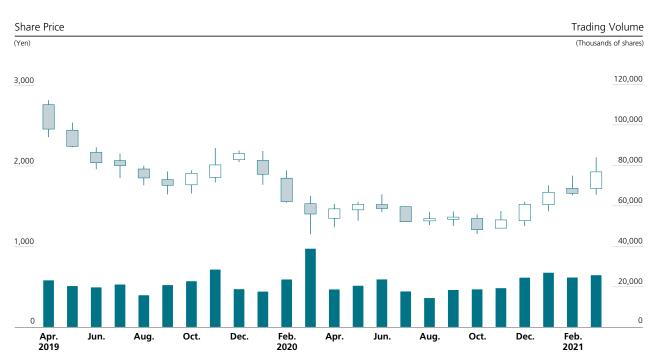
# **Shareholder Data**

Principal shareholders (As of March 31, 2021)					
Name of Shareholders	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)	31,715	7.98			
Inabata & Co., Ltd.	16,782	4.22			
Custody Bank of Japan, Ltd. (Trust account)	12,828	3.23			
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			
Custody Bank of Japan, Ltd. (Trust account 7)	4,145	1.04			
Sumitomo Dainippon Pharma Employee shareholders' association	2,934	0.74			
Aioi Nissay Dowa Insurance Co., Ltd.	2,661	0.67			

#### Composition of shareholders (As of March 31, 2021)



#### Share price range and trading volume



# 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<sup>®</sup> 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, 2020 and 2021.

# **2021** 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<sup>®</sup>) Sector and is designed to target companies that have high Environmental, Social and Governance (ESG) performance. Sumitomo Dainippon Pharma has been independently assessed according to the MSCI Japan ESG Select Leaders Index criteria, and has continuously satisfied the requirements to become a constituent of this index since 2017.

# **2021** 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.



# **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.



# 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.



# 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 2020, Sumitomo Dainippon Pharma was selected as one of the ESG Management Leading Companies and received a Silver Class award as one of the top 21 to 50 companies selected.





# 2021 CONSTITUENT MSCI JAPAN EMPOWERING WOMEN INDEX (WIN) ESG SELECT LEADERS INDEX





**FTSE Blossom** Japan



Sompo Sustainability Index





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



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

2021 CONSTITUENT MSCI JAPAN

Issued in December, 2021