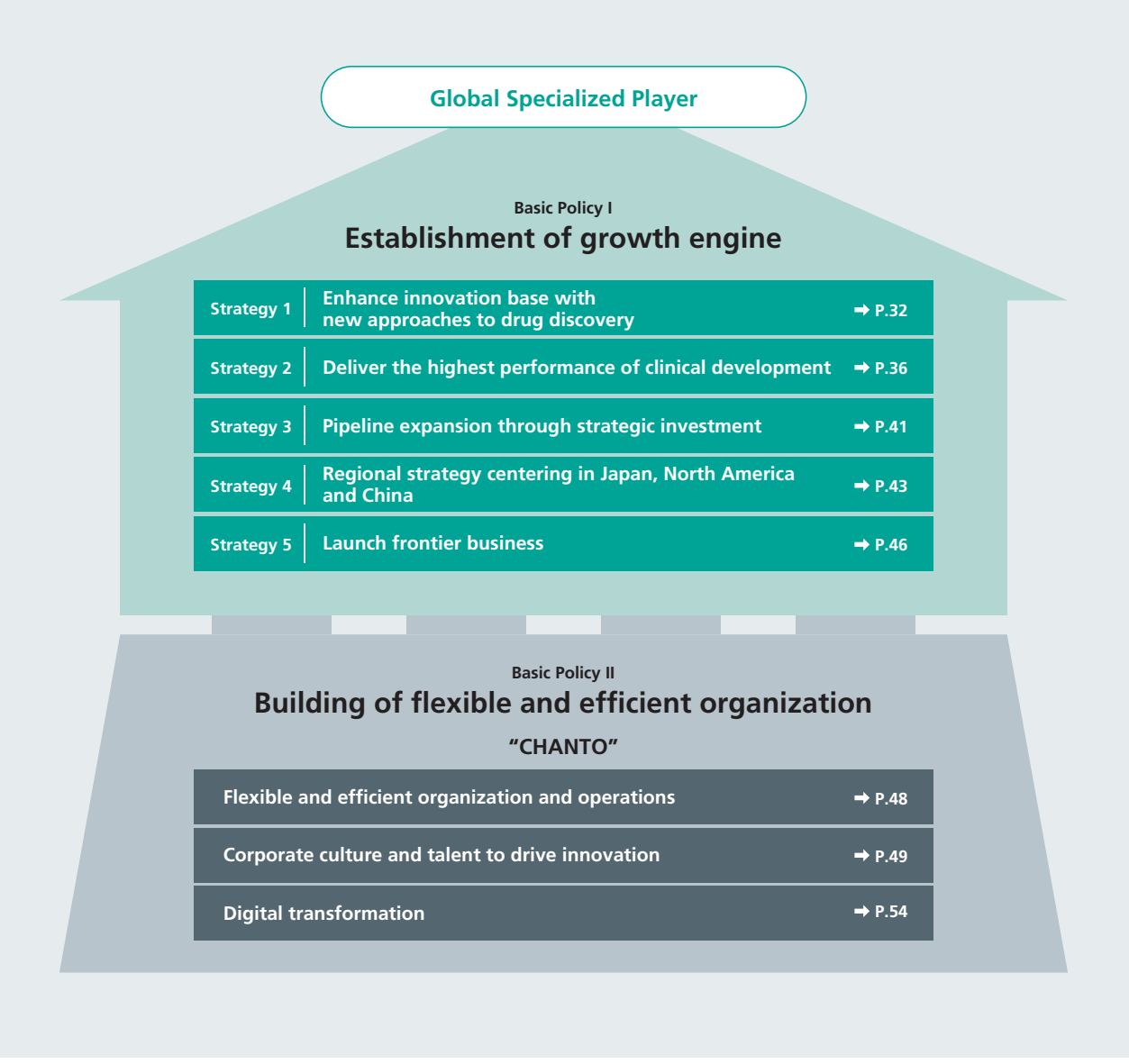
Mid-term Business Plan 2022: Reshaping the Business Foundation

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 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

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

Basic Policy I

Establishment of growth engine

Strategy 1 Enhance innovation base with new approaches to drug discovery

1 **Prioritize the three focus areas + Infectious diseases and Vaccines**

2 **Accelerate external collaboration**
Psychiatry & Neurology | Oncology | Regenerative / Cell | Infection

3 **Explore innovation leveraging by digital technologies and big data**
Psychiatry & Neurology | Oncology | Regenerative / Cell | Infection

4 **Engage in initiatives to realize Precision Medicines**
Psychiatry & Neurology | Oncology | Regenerative / Cell | Infection

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
- **Continuous development of pharmaceuticals in areas with high unmet medical needs**
- **Development of healthcare solutions to respond to the future healthcare needs centered on areas where synergies with the pharmaceutical business can be expected**

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.

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 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

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**

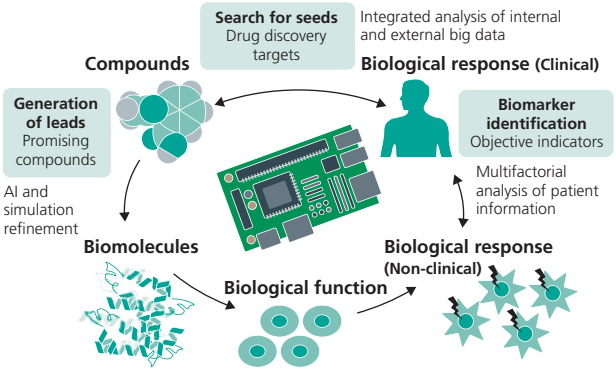
Enhance probability of success in clinical studies
Sumitomo Dainippon Pharma 15%
(6-8% industry average)
Further improvement by utilization of biomarkers

Expand early pipeline
12 candidates in the past 3 years
4 of them are in clinical development

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.



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.

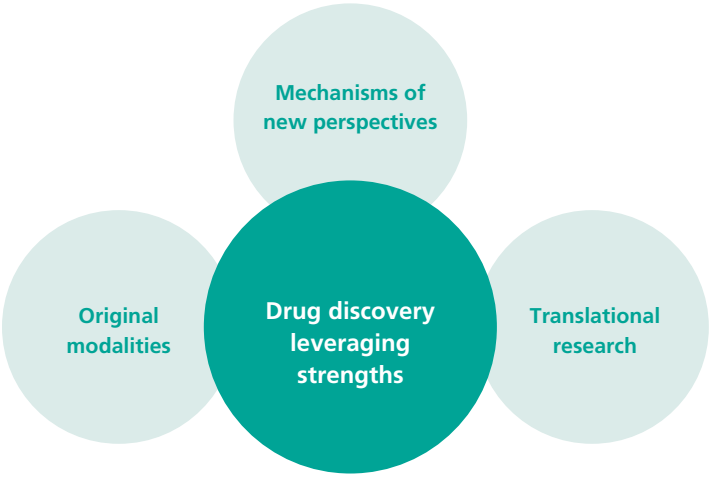
First, we will focus on drug discovery targets that enable us to obtain early clinical POC with clearly targeted patients while also seeking to select drug discovery targets by using clinical information big data analysis and patient-derived samples. The second is the acquisition of technologies such 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

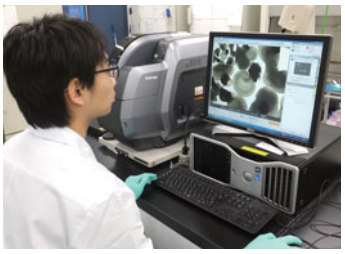
Pursue advanced manufacturing expertise and cutting-edge science to become a global leader

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 m², 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

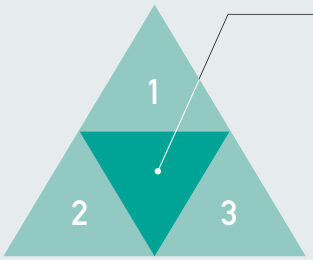
We are implementing development of adjuvanted vaccines by combining TLR7 agonist adjuvant, our foundation technology, with promising antigens from outside research institutes. We are working on malaria vaccines with Ehime University, etc. and a universal influenza vaccine with the National Institutes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

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

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

Strategy 2 Deliver the highest performance of clinical development



Strengthen our capability to ensure the highest performance ("CHANTO")

1	**Goal setting for securing success**
2	**Management of business risk**
3	**Adopting cutting-edge technology**

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

Material issues **Development of innovative products and healthcare solutions / Contributing to the development of science**

Targets
- **Continuous development of pharmaceuticals in areas with high unmet medical needs**
- **Development of healthcare solutions to respond to the future healthcare needs centered on areas where synergies with the pharmaceutical business can be expected**

KPIs
- **Progress on main development pipeline:** Progress targets for key development products are set to help create pharmaceutical products and medical solutions on a consecutive basis.
- **Progress on early-stage development pipeline:** In the Psychiatry & Neurology and Oncology areas, the number of clinical transitions to Phase 2 is set as the indicator.
- **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.

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)

Psychiatry & Neurology area ····· New compounds under development: 10

Development products	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)

Oncology area ····· New compounds under development: 9

Development products	Proposed indication	Development stage	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	Pulmonary arterial hypertension (PAH)	Phase 2	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)

Features of major products under development

ulotaront (SEP-363856)

Ulotaront is a TAAR1 (trace amine-associated receptor 1) agonist with serotonin 1A (5-HT$_{1A}$) 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-HT$_7$ activity intended to enhance antidepressant efficacy and to produce reduced levels of dopamine D$_2$ 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®, 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

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.

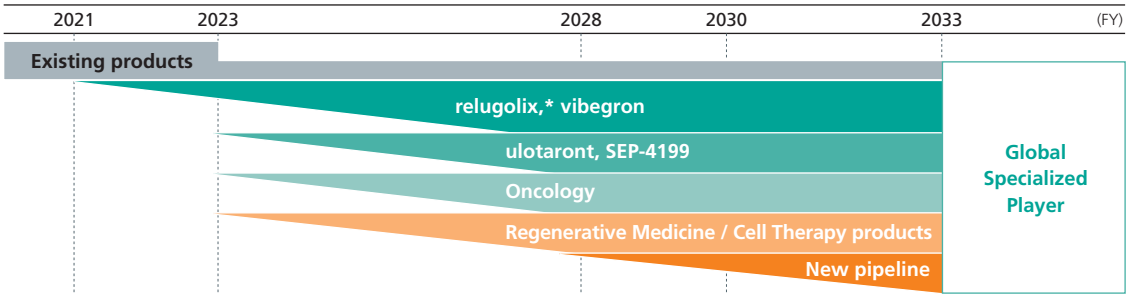
Empowering the research organizations and developing human resources who will lead the future

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.

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**

Consideration

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

Stock Acquisition

Sumitovant Biopharma

- Myovant Sciences*2
- Urovant Sciences
- Enzyvant Therapeutics
- Altavant Sciences
- Spirovant Sciences

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 (Myovant)	Small molecular	ORGOVYX®	Advanced prostate cancer	Oncology	U.S.	January 2021
	Small molecular (combination tablet)	MYFEMBREE®	Uterine fibroids	Women's health	U.S.	June 2021
vibegron (Urovant)	Small molecular	GEMTESA®	Overactive bladder (OAB)	Urology	U.S.	April 2021

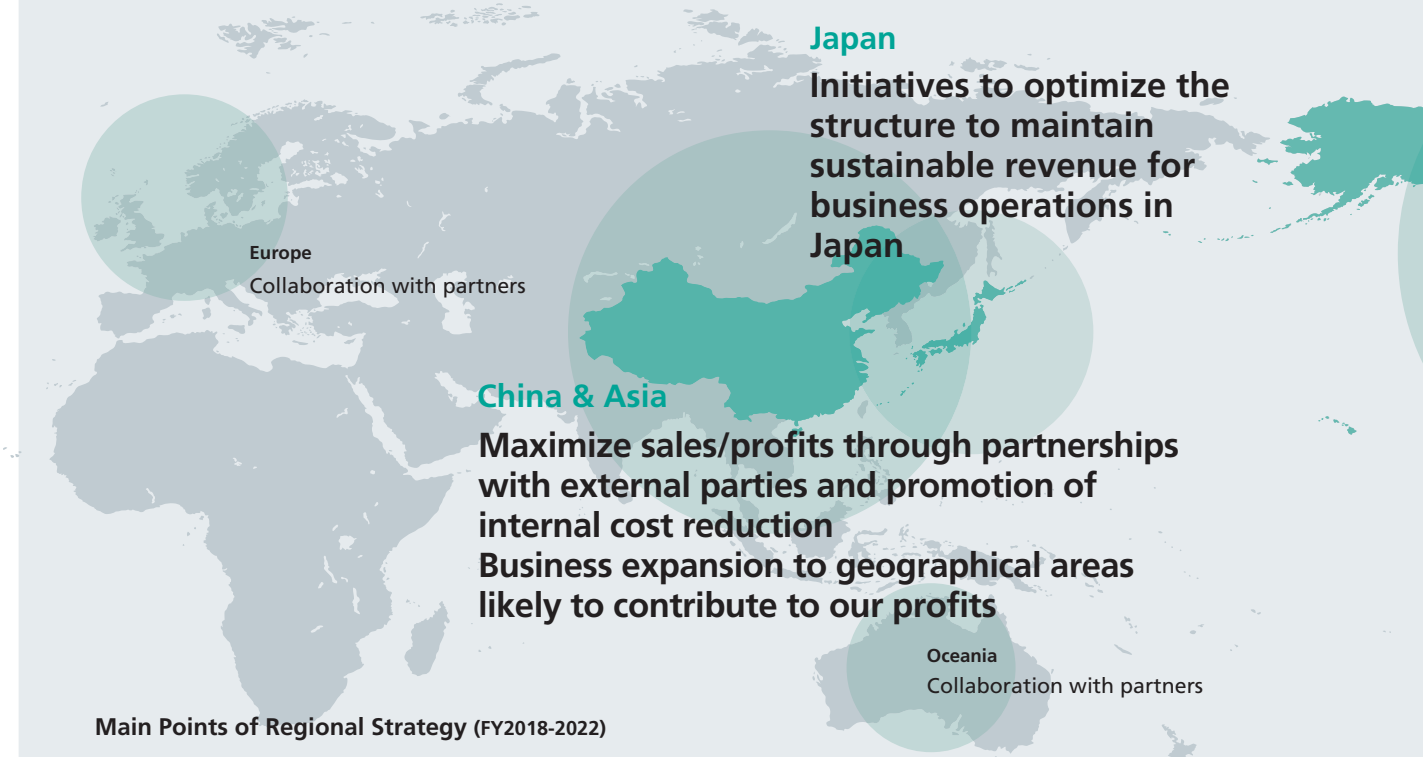
Development pipelie acquired through the strategic alliance with Roivant (as of July 29, 2021)

Compound	Modality	Indication	Therapeutic area	Development phase	Milestone
relugolix (Myovant)	Small molecular	Advanced prostate cancer	Oncology	MAA submitted (Europe)	MAA approval (Europe)
	Small molecular (combination table)	Uterine fibroids	Women's health	MAA approved (Europe)	Launches in EU countries (by Gedeon Richter Plc.)
		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
vibegron (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 (Altavant)	Recombinant protein	Bronchiolitis obliterans syndrome (BOS)	Respiratory	Preclinical	IND submission (2023)
		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

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



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)

Japanese Market

Transform to steady growth
- Maximize product value in the Diabetes area (Trulicity®, Equa®/ EquMet®, and TWYMEEG®)
- Maximize product value in the Psychiatry & Neurology area (TRERIEF®, LATUDA®, and LONASEN® Tape)

Initiatives to optimize the structure to maintain sustainable revenue for business operations in Japan
- Business operation based on the assumption of shrinkage of the size of pharmaceutical market in Japan
- Review global head office functions for optimization
- Maximize sales/profits through partnerships with external parties and promotion of internal cost reduction

North American Market

Maximize product value in the Psychiatry & Neurology area
- Maximize value of LATUDA® and product value of KYNMOBI® while maintaining growth of APTIOM®
- Accelerate development of ulotaront (SEP-363856) and other pipeline assets including SEP-4199

Expedite efforts to establish new products owned by Sumitovant and Myovant as growth drivers
- Achieve smooth market penetration and maximize product value of ORGOVYX® MYFEMBREE® and GEMTESA®

Pursue opportunities for strategic investment & 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

North America

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® and LATUDA® 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® Tape (Schizophrenia): Launched
- RETHIO® (Conditioning treatment prior to autologous hematopoietic stem cell transplantation (HSCT)): Launched

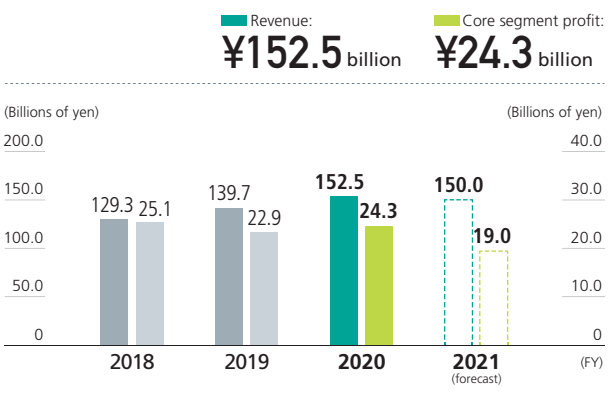
FY2020
- LATUDA® (Schizophrenia, bipolar depression): Launched
- Activities of online MR™ and vMR® started
- LONASEN® tablet/powder (Schizophrenia in children): Dosage and administration added
- S-RACMO Co., Ltd. established (CDMO business in the Regenerative Medicine / Cell Therapy field)

FY2021
- TWYMEEG® (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®, which was launched in June 2020, and in the latter, we will expand sales of Equa® and EquMet®, as well as Trulicity®, while at the same time preparing for the launch of TWYMEEG® (approved in June 2021) scheduled for September 2021.

Revenue / Core segment profit



Mid-term Business Plan 2022

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

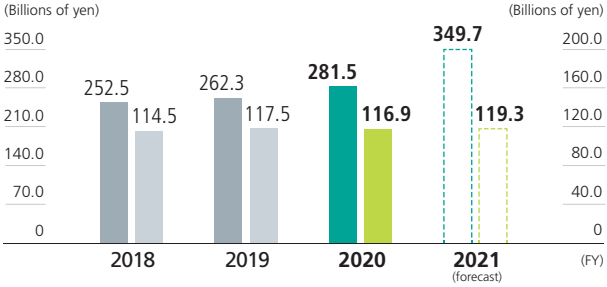
FY2021
- GEMTESA® (Overactive bladder): Launched
- MYFEMBREE® (Uterine fibroids): Launched

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: ¥281.5 billion　Core segment profit: ¥116.9 billion



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® (Schizophrenia): Launched (China)

FY2020
- Sumitomo Pharmaceuticals Taiwan Co., Ltd. established (SPAP's subsidiary in Taiwan)

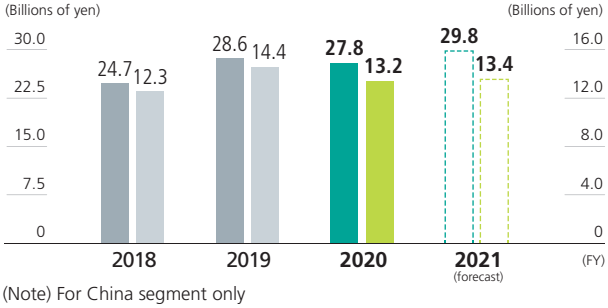
FY2021
- Lefamulin and other development compounds in-licensed

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.

Revenue / Core segment profit

Revenue: ¥27.8 billion　Core segment profit: ¥13.2 billion



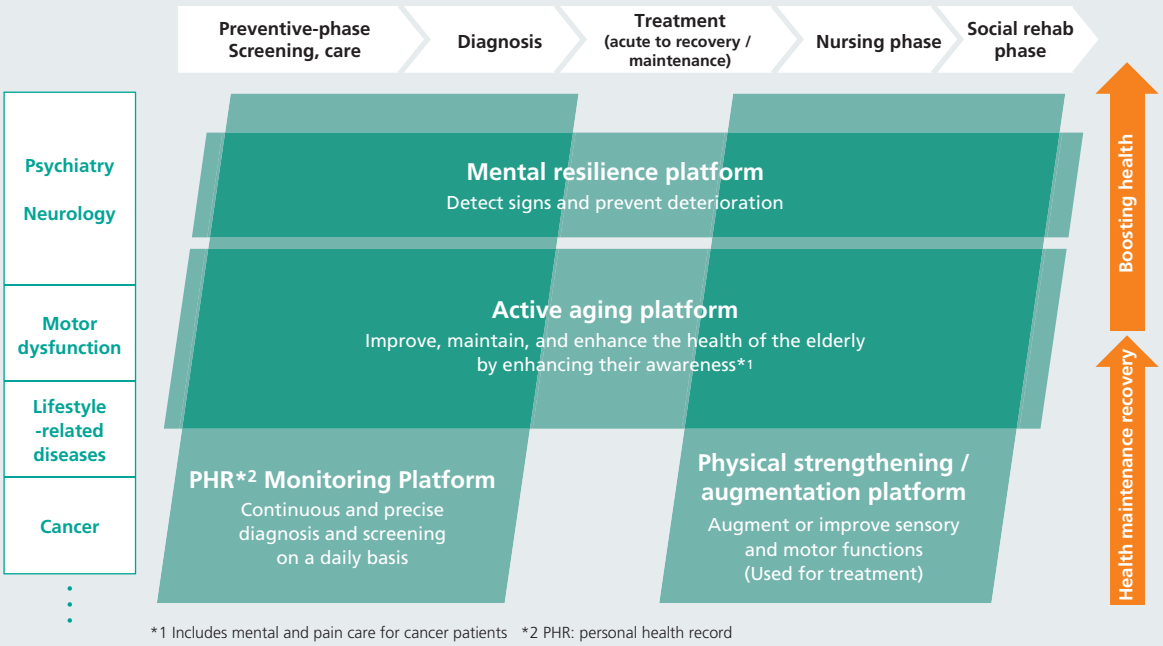
(Note) For China segment only

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

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.



*1 Includes mental and pain care for cancer patients *2 PHR: personal health record

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)