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 Pharma has set targets and KPIs, and we have provided a list of them on pages 35–38.

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 Best in class initiatives focused on value**

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

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

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

In addition to R&D in three research focus areas (Psychiatry & Neurology, Oncology, and Regenerative Medicine/Cell Therapy), Sumitomo 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 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 Sciences Ltd. (hereinafter, "Roivant").

Engage in initiatives to realize Precision Medicines

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

Targets · KPIs

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

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 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.

➡ Please see page 35 for KPI progress in fiscal 2021.

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, patient-derived iPS cells, and neural circuit evaluation technologies, we will work to develop innovative therapeutic agents for psychiatric disorders in areas of high unmet need, neurodegenerative disease and rare 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 area

We will focus on research and development for things such as the treatment of schizophrenia, depression, developmental disorders, and psychiatric symptoms in neurological disorders considering 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 area

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. We will also develop treatments for peripheral symptoms of neurodegenerative diseases.

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 Pharma 15% **(6-8% industry average)**

Further improvement by utilization of biomarkers

Expand early pipeline

12 candidates in the past 4 years

5 of them are in clinical development

Exploratory/development research using cutting-edge technology

We are working to identify new targets for drug discovery through translational research using a range of clinical data (evaluation scores, brain wave and image data, etc.) obtained during the development of LATUDA® and ulotaront, 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 testing the effectiveness of compounds in disease model animals using optical genetics technology to activate certain neural circuits, and are identifying neural circuits targeted by compounds using brain imaging technology.

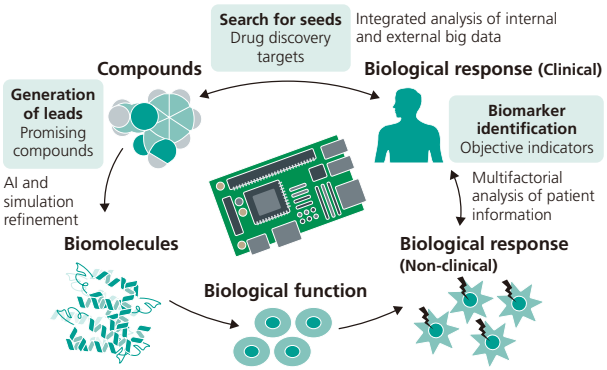
Furthermore, we are tackling new challenges such as the utilization of real-world data using DrugOME, acquired from Roivant, the utilization of evaluation systems that reflect human pathologies prepared using patient-derived iPS cells, and the development of new modalities beyond small molecules.

As a result of these initiatives, in fiscal 2021 we were able to advance two compounds into clinical phase and numerous compounds into the preclinical phase.

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.



Organizational structure to support product creation on a consecutive basis (psychiatry & neurology area and infectious diseases area)

We are promoting an organizational structure that supports product creation, such as the new Research Project System adopted to allow researchers who have come up with project themes to serve as Project Leaders

up to the early clinical development stage, as well as cross-sectional virtual one-team activities to solicit ideas beyond the boundaries of our organizations. To date, DSP-0038, DSP-9632P, DSP-0187, DSP-3456, and KSP-1007, all 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 and strike an appropriate balance between investment and return by, for example, acquiring data that allow us to make decisions on stage transition from early on, as well as bolstering efforts to identify optimum cancer types/patients in short-term, small-scale studies.

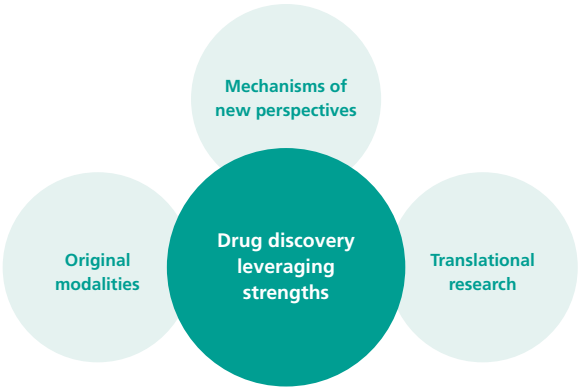
Over the last roughly 10 years, we have focused on building up the base of new modality technologies. By steadily implementing these technologies into drug discovery, we are aiming to establish a platform to achieve the sustained production of candidate compounds for development. We will develop highly competitive R&D pipelines by matching the best modalities with highly distinctive targets for drug discovery selected in collaboration with academia and by using digital technologies such as DrugOME. We are also stepping up our translational research by means that include working with academia and feeding our clinical development data back into translational research.

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 expansion and improvement of new drug discovery modality technologies. 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. Lastly, we will maintain and bolster our coordination with academia. We will make use of the information we gain from key opinion leaders to formulate early clinical development strategies. We will also use it to find targets for drug discovery that have strong relevance to cancer pathology.

Initiatives to develop a pipeline with a competitive edge



Strengthening the global R&D structure

We aim to develop innovative products on an ongoing basis under a global R&D structure consisting of the Cancer Research Unit and the Oncology Clinical Development Unit in Japan, as well as the Sumitomo Pharma Oncology, Inc. in the United States. We will focus on developing new cancer drugs using new modalities in collaboration with the Modality Research Unit established in fiscal 2022.

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

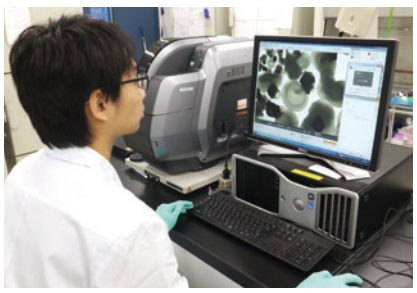
Basic Policy I

Establishment of growth engine

model, which pursues advanced industrialization and manufacturing expertise, and cutting-edge science. Thus, we are implementing five 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 Pharma 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 allogeneic 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 clinical study materials, we plan to carry out commercial production after obtaining approval. Furthermore, in 2022 we have started the construction of a manufacturing plant in the U.S. for cell therapy products. The facility will manufacture "RETHYMIC®," an allogeneic cultured thymus tissue for which consolidated subsidiary Enzyvant Therapeutics Ltd. has obtained approval from the U.S. Food and Drug Administration (FDA). We plan to also make the facility capable of producing allogeneic iPS cell-derived products, which we are looking to commercialize.



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 radical therapies for diseases for which only symptomatic relief and temporary suppression of progression have been available to date. To this end, we are also 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 to contribute to global health

Through joint research with academia and others, we will contribute to global health and aim for commercialization during the next MTBP period (fiscal 2023–2027).

Main Projects

Drug discovery to treat antimicrobial resistance (AMR) bacterial infections

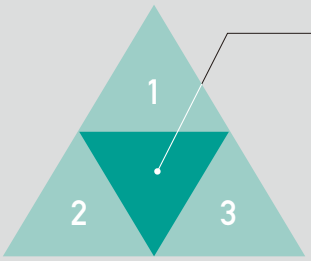
We are promoting joint drug discovery research with The Kitasato Institute to treat antimicrobial resistance (AMR) bacterial infections covered by the Japan Agency for Medical Research and Development (AMED) CiCLE (Cyclic Innovation for Clinical Empowerment) program. KSP-1007, which was developed through this project, advanced to clinical study in the U.S.

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

Strategy 2 Deliver the highest performance of clinical development



Strengthen our ability to deliver 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 collaborated with alliance partner Otsuka Pharmaceutical and set goals to maximize the compound's value, 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. Sumitomo Pharma and Sunovion signed a licensing agreement in September 2021 with Otsuka Pharmaceutical for the joint development and worldwide commercialization of four new candidate compounds in the Psychiatry & Neurology area that include ulotaront and SEP-4199. Ulotaront is currently in phase 3 studies for schizophrenia while SEP-4199 is in phase 3 studies for bipolar I depression. Working with Otsuka Pharmaceutical will allow us to more rapidly and reliably develop these compounds into drugs of value and enable us to contribute to the treatment of more patients around the world.

In the Oncology area, we are strengthening our efforts to identify optimal indications in small-scale studies, as well as actively promoting partnership and out-licensing activities.

Targets · KPIs

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

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.

➡ Please see page 35 for KPI progress in fiscal 2021.

Basic Policy I

Establishment of growth engine

Adopting cutting-edge technology and utilizing the regulatory system

In the Psychology & Neurology area, we use biomarkers to make decisions about whether or not to proceed at an early stage. By utilizing data from past studies, 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 medicinal product designation system, and breakthrough therapy designation system.

Development pipeline (as of July 29, 2022, not including drugs with additional indications and usages)

Psychiatry & Neurology area ····· New compounds under development: 12

Development products	Proposed indication	Development stage	Region	Launch target
ulotaront (SEP-363856)	Schizophrenia	Phase 3 Phase 2/3	U.S. Japan China	FY2024 (U.S.) FY2026 (Japan)
SEP-4199	Bipolar I depression	Phase 3	U.S. Japan	Latter half of the 2020s (U.S.)

Oncology area ····· New compounds under development: 8

Development products	Proposed indication	Development stage	Region	Launch target
DSP-7888	Solid tumors	Phase 1/2	U.S.	TBD
dubermatinib (TP-0903)	Acute myeloid leukemia (AML)	Phase 1/2	U.S.	TBD

Regenerative medicine/cell therapy field ····· Number of projects: 5

Projects	Proposed indication	Development stage	Region	Launch target
Allo iPS cell-derived dopamine neural progenitor	Parkinson's disease	Phase 1/2 (Investigator-initiated study)	Japan	FY2024*
HLCR011 (Allo iPS cell-derived retinal pigment epithelium)	Age-related macular degeneration (AMD)	Preparing for start of clinical study	Japan	FY2025*

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

Other area ····· New compounds under development: 5

Development products	Proposed indication	Development stage	Region	Launch target
lefamulin	Bacterial community acquired pneumonia	NDA submitted	China	FY2024
rodatristat ethyl	Pulmonary arterial hypertension (PAH)	Phase 2	U.S.	Latter half of the 2020s

Features of major products under development

ulotaront (SEP-363856)
Ulotaront has the potential to be highly effective with positive and negative symptoms of schizophrenia, and result in a low frequency of extra pyramidal reactions due to a mechanism of action that does not act against dopamine receptors. Phase 2 study results supported efficacy in positive and negative symptoms of schizophrenia, with adverse reactions similar to placebo. Notably, ulotaront was not associated with extrapyramidal symptoms, weight gain, increases in lipids or glucose, and prolactin elevation. Ulotaront has received U.S. FDA Breakthrough Therapy designation. We expect it to grow into a blockbuster at its peak, including for additional indications.

SEP-4199
SEP-4199 is a non-racemic ratio of amisulpride enantiomers. SEP-4199 is designed to reduce levels of dopamine D_2 receptor occupancy to levels appropriate for the treatment of bipolar depression by increasing the ratio of R-amisulpride to S-amisulpride. With a dopamine receptor occupancy that is the minimum necessary to achieve an effectiveness equal to or better than existing formulations, it is expected to result in a low frequency of extrapyramidal adverse reactions. It may also become a new option for treating bipolar disorder for which insufficient treatment options exist.

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.

Allogeneic iPS cell-derived drugs
We are working with partners in industry and academia to advance our business involving regenerative medicines and cell therapies using allogeneic iPS cells (from healthy donners) that target Parkinson's disease, age-related macular degeneration, retinitis pigmentosa, spinal cord injuries, and kidney 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 aim to begin clinical studies in the U.S. during fiscal 2022.
Age-related macular degeneration: Joint development with Healios K.K.

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

Infectious diseases
We are currently developing KSP-1007 with the goal of creating a therapeutic drug for antimicrobial resistant (AMR) bacterial infections. We are also working with partners to advance universal influenza and malaria vaccine projects (preclinical trial stage).
We aim to commercialize them from the next Mid-term Business Plan period (fiscal 2023–2027) onward.

Basic Policy I

Establishment of growth engine

Message from the Executive Officers (Regenerative Medicines/Cell Therapy field)

Toru Kimura

Representative Director,
Executive Vice President
Global Corporate Strategy; Regenerative & Cellular Medicine Office; Regenerative & Cellular Medicine Kobe Center; Regenerative & Cellular Medicine Manufacturing Plant

Establishing a business process covering R&D to manufacturing and sales

Sumitomo Pharma is undertaking multiple projects in the field of Regenerative Medicine/Cell Therapy with the goal of achieving ¥200 billion in annual revenues globally by around 2030.

In October 2021, we obtained approval in the U.S. for RETHYMIC®, an allogeneic processed thymus tissue and our first cell product as a product for immune reconstruction in pediatric patients with congenital athymia, beginning sales in March 2022. Then in April 2022, we made the decision to build a cell processing center (CPC) compliant with cGMP regulations in the U.S. Slated for completion in fiscal 2023, the CPC is being built to manufacture RETHYMIC® and regenerative medicine/cell therapy products derived from allogeneic iPS cells, which we are seeking to commercialize.

While our regenerative medicine/cell therapy business was a foray into the unknown for us, we are very satisfied with our progress in establishing business processes that include R&D, manufacturing, and sales.

Building up expertise in commercializing Regenerative Medicine/ Cell Therapy products as a front runner

The Regenerative Medicine/Cell Therapy field involves very different business models from the conventional pharmaceuticals business, and gaining expertise here can only be done through the process of commercialization.

In 2013, we made a full-scale entry into the Regenerative Medicine/Cell Therapy field ahead of other companies. Along with steady R&D, in 2018 we also built “SMaRT,” the world's first Regenerative Medicine/Cell Therapy manufacturing plant to serve as a commercial manufacturing facility for Regenerative Medicine/Cell Therapy products derived from allogeneic iPS cells in Japan. These efforts are a source of pride as we establish ourselves as a world leader in the field of iPS cell-based Regenerative Medicines/Cell Therapy.

We are currently conducting five projects involving iPS cells, and we expect to have a couple of new products approved during the period of the next Mid-term Business Plan. We will continue to get products to market before the competition, laying down a technological foundation and acquiring business management expertise as we develop the Regenerative Medicine/Cell Therapy field into a successful business that supports the future growth of the Sumitomo Pharma Group.

New challenges in unfamiliar fields nurture talent

In interacting with employees, it has occurred to me that carrying out our business in the Regenerative Medicine/Cell Therapy field helps develop the "professionals who are proactive in adapting to changes and taking on a challenge" that Sumitomo Pharma is looking for.

As this is a new business for us, trying to apply expertise gained through our prior pharmaceuticals business will not work in R&D, manufacturing, or sales. Work that requires taking on new challenges encourages ingenuity and broadens employees' horizons.

I believe such an environment provides good opportunities for employees to grow and for the Sumitomo Pharma Group to strengthen its competitiveness for the future.

Message from the Executive Officers (Psychiatry & Neurology, Oncology areas)

Yoshiharu Ikeda
Member, Board of Directors, Senior Executive Officer
Cancer Research; Modality Research; Drug Research Division
Head of Japan Business Unit

Upgrading our pipeline and advancing R&D through strategic investment

In the Psychiatry & Neurology and Oncology areas, R&D is challenging and unmet medical needs are extremely high. In Mid-term Business Plan 2022, we were unable to launch and maximize the profit potential of key products that we had high hopes for after LATUDA® LOE and that would fuel future growth in the areas of Psychiatry & Neurology and Oncology. These factors contributed to a significant change in our business forecasts.

Meanwhile, we have acquired post-LATUDA products through a strategic alliance with Roivant and are making steady progress with late-stage clinical development for compounds such as ulotaront and SEP-4199, which have good mid- to long-term earnings potential. As in-house drug discovery achievements, I feel that our efforts to improve and expand on our early-stage development pipeline, as well as our progress with modality research, have met with a very good response. Starting with the Oncology area, we are developing new modality technologies and implementing them in drug discovery. Going forward, I am hopeful that we will advance R&D in the Psychiatry & Neurology and Oncology areas by expanding our unique foundation technologies and leveraging in silico technologies and digital technologies.

Developing the talent that will create cutting-edge technologies and maximize their potential

In the pharmaceutical business, it takes between 10 and 15 years and an investment of more than ¥100 billion to develop a new pharmaceutical from the research stage. By pursuing drug discovery using a network with external players and by utilizing big data and digital technologies, we are working to further improve R&D efficiency and the probability of successful clinical developments.

The talents in charge of this process are becoming increasingly important as drug discovery technologies become more sophisticated. Since I believe that talents are the most important capital for a company, we are working to create systems that give highly ambitious employees opportunities to challenge themselves.

For example, in the Psychiatry & Neurology area, we have instituted a new "Research Project System", whereby, in the general case, researchers who have conceived of a project theme serve as Project Leaders up to the clinical stage. We are also conducting cross-sectional "Virtual One-Team Initiatives" comprising ambitious participants to solicit ideas beyond the boundaries of our organizations. Although we do of course sometimes fail in our R&D pursuits, but the role of management includes fostering a corporate culture that acknowledges those failures and encourages taking on new challenges. Along with these initiatives, we will work with the R&D teams at our foreign subsidiaries, carry out overseas personnel transfers, and conduct interviews with key opinion leaders. Through such efforts, we will develop talent capable of not only carrying out R&D but also running our global business.

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 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, 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").

Under the strategic alliance, besides acquiring all of the shares of Sumitovant Biopharma Ltd. ("Sumitovant"), a new company to which the shares of Roivant's five subsidiaries have been transferred, Sumitomo 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. We subsequently invested roughly ¥30 billion in, among other things, acquiring Urovant Sciences as a subsidiary, and made close to ¥150 billion in upfront investments (recorded on profit-loss statements) in Sumitovant through fiscal 2021. This resulted in a total investment of ¥510 billion.

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 research focus 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 is a compound owned by Myovant Sciences Ltd. The Sumitomo Pharma Group owns approximately 52% 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 Mid-term Business Plan 2022, 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**
- **Urovant Sciences • Enzyvant Therapeutics**
- **Altavant Sciences • Spirovant Sciences**

Healthcare Technology Platforms Transfer

- **DrugOME • Digital Innovation**

+

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

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

North America
Establish post-LATUDA growth trajectory by maximizing on market products and promoting development of promising novel compounds

China & Asia
Strengthen and develop local subsidiary functions and maximize sales of marketed products through partnerships with external parties; reduce internal costs and expand business into geographical areas likely to contribute to profits

Europe, etc.
Collaboration with partners

Japanese market

SWOT

Strength
- Industry-leading sales revenue in the diabetes area and provision of neutral information based on an expansive product lineup
- Long-developed pharmaceutical R&D capabilities in the psychiatry & neurology area, and proposals for therapies based on actual cases using specialized MR
- Pursuit of digital transformation and promotion of products according to customer needs through online MR

Opportunity
- High unmet medical needs in the psychiatry & neurology area
- Opportunities to market other companies' products using our robust infrastructure
- Increasing opportunities to gather information digitally from healthcare professionals

Weakness
- Declining profit ratio due to a changing product mix

Threat
- Declining sales revenue and profits due to decreasing drug prices every year
- Declining sales of long-listed products due to an earlier-than-expected penetration of generic drugs

Main points of our regional strategy

Achieve a growth trajectory
- Maximize product value in the Diabetes area (Equa®/EquMet®, and TWYMEEG®)
- Maximize product value in the Psychiatry & Neurology area (TRERIEF®, LATUDA®, and LONASEN® Tape)

Optimize the structure for ensuring sustained earnings
- Build a structure appropriate to pharmaceutical market size
- Optimize global head office functions
- Maximize sales/profits through partnerships with external parties, and reduce internal costs

Achievements from FY2018 through July 31, 2022

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
- Started activities of online MR™ and vMR®
- LONASEN® tablet/powder (Schizophrenia in children): Dosage and administration added
- Established S-RACMO Co., Ltd. (CDMO business in the Regenerative Medicine/Cell Therapy field)

FY2021
- TWYMEEG® (Type 2 diabetes): Launched
- METGLUCO® (Type 2 diabetes): Public knowledge-based application for additional infertility treatment-related indications
- Agalsidase Beta BS I.V. Infusion [JCR] (Fabry Disease): Marketing alliance

Business activities in the Japan segment

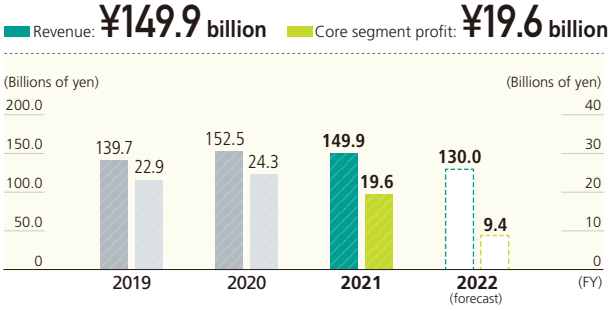
In response to a market environment that is becoming increasingly challenging due to policies to curb drug costs, including the commencement of the off-cycle NHI drug price revision, we will further increase the efficiency of our business operations. We will maximize our product value in the Psychiatry & Neurology and Diabetes areas to

Basic Policy I

Establishment of growth engine

become a genuinely dominant player in both of these focus areas. In the Psychiatry & Neurology, we will expedite market penetration of LATUDA®, which was launched in June 2020, and in Diabetes, we will expand sales of Equa® and EquMet®, while at the same time furthering the market penetration of TWYMEEG®, which launched in September 2021.

Revenue / core segment profit



North American market

SWOT

Strength
- Capabilities of development and sales in Psychiatry & Neurology
- Best in class, late-stage assets focusing on value as well as talents who lead that business

Opportunity
- Enhancement of our innovation base and pursuit of digital transformation through the DrugOME and Digital Innovation technology platforms

Weakness
- Early maximization of new products will be a challenge

Threat
- LATUDA® LOE in the U.S. (slated for February 2023)

Main points of our regional strategy

Maximize product value in Psychiatry & Neurology
- Maximize LATUDA® profits and grow sales of KYNMOBI® and APTIOM®
- Promote the development of late-stage assets, including ulotaront

Further efforts to establish new products as growth drivers
- Maximize the product value of ORGOVYX®, MYFEMBREE®, GEMTESA®, and RETHYMIC®

Promote strategic investment and partnerships with other companies
- Expand pipelines and maximize value of internal assets
- Promote sales partnerships

Optimize business operations
- Improve business infrastructure and systems
- Realize cost synergies by strengthening coordination among subsidiaries

Achievements from FY2018 through July 31, 2022

FY2018
- LONHALA® MAGNAIR® (COPD): Launched

FY2019
- Acquired the shares of 6 subsidiaries through the strategic alliance with Roivant

FY2020
- Sumitomo Dainippon Pharma Oncology, Inc. (currently, Sumitomo 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 with Pfizer Inc. for relugolix.
- ORGOVYX® (Advanced prostate cancer): Launched

FY2021
- GEMTESA® (Overactive bladder): Launched
- MYFEMBREE® (Uterine fibroids): Launched
- RETHYMIC® (pediatric congenital athymia): Launched

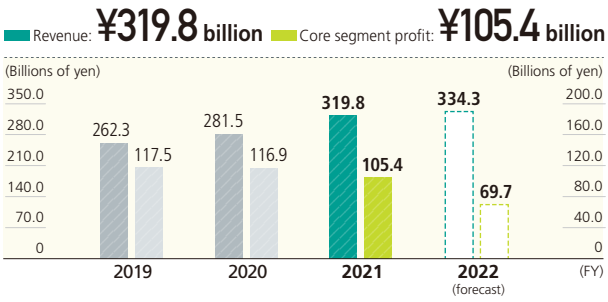
Business activities in the North America segment

Sunovion Pharmaceuticals Inc. ("Sunovion") and the Sumitovant Group run its business operations in North America pursuing establishment of post-LATUDA growth trajectory. Sunovion focuses on maximization of LATUDA®, the biggest pillar of the Sumitomo Pharma Group's earnings, further growth of APTIOM®, as well as KYNMOBI®, which was launched in September 2020. The Sumitovant Group's focus is quicker 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 on market penetration of GEMTESA®, which was launched in April 2021. In so doing, we are striving for efficient sales and marketing for Myovant and Urovant by leveraging Sunovion's robust sales infrastructure. Enzyvant Therapeutics makes effort for delivering RETHYMIC®, which was launched in March 2022, to patients who are waiting for the therapy as soon as possible.

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

Revenue / core segment profit



Chinese & Asian market

SWOT (China)

Strength
- Strong business foundation (competent staff, business expertise)
- Handles high quality, competitive Sumitomo Pharma products such as MEROPEN®)

Opportunity
- Develop systems to help accelerate new drug approval and protect patents
- Sustainable growth potential for the pharmaceuticals market due to economic growth, healthcare infrastructure improvements, etc.

Weakness
- Expanding the lineup of launched products that have a medium- to long-term growth track will be an issue

Threat
- Further drug cost reduction measures are being taken
- Rising country risk attributable to worsening international relations, etc.

Main points of our regional strategy

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 promote internal cost reduction
- Strengthen local subsidiary functions and expand business into geographical areas likely to contribute to profits
- Pursue business opportunities in the Regenerative Medicine/Cell Therapy field, Frontier business, Oncology area, etc.

Further expand China business
- Reinforce business infrastructure as the third pillar
- Maximize revenue from existing products
- Rebuild our business foundation and launch new products in anticipation of future market changes
- Participate in global development projects

Reinforce business in East and Southeast Asia
- Reinforce business functions at subsidiaries in Singapore, Thailand, and Taiwan
- Launch and develop functions at our Malaysian subsidiary
- Maximize revenue from MEROPEN® and LATUDA® and launch new products

Achievements from FY2018 through July 31, 2022

FY2018
- Reinforced functions of subsidiary in Singapore
- Established local subsidiary in Thailand

FY2019
- LATUDA® (schizophrenia): Launched (China)

FY2020
- Established local subsidiary in Taiwan

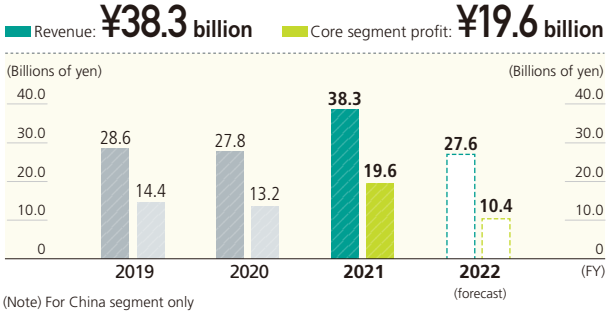
FY2021
- In-licensed lefamulin and other development compounds
- Opened representative office in Vietnam
- Established local subsidiary in Malaysia

FY2022
- Established holding company in China

Business activities in the China & Asia segment

The Sumitomo Pharma Group is reinforcing our business foundations in China, the third pillar of our business, while at the same time securing growth potential by continuing to consolidate our foothold in the Asian market. In the China segment, although measures to reduce drug costs continue to be taken, we will maximize the value of our current products while actively launching new products in order to achieve further growth. In East and Southeast Asia, we will strive to maintain and expand sales of MEROPEN® and LATUDA® by promoting sales through our subsidiaries and collaborating with respective partner companies, while launching new products aimed at achieving sustainable future growth.

Revenue / core segment profit



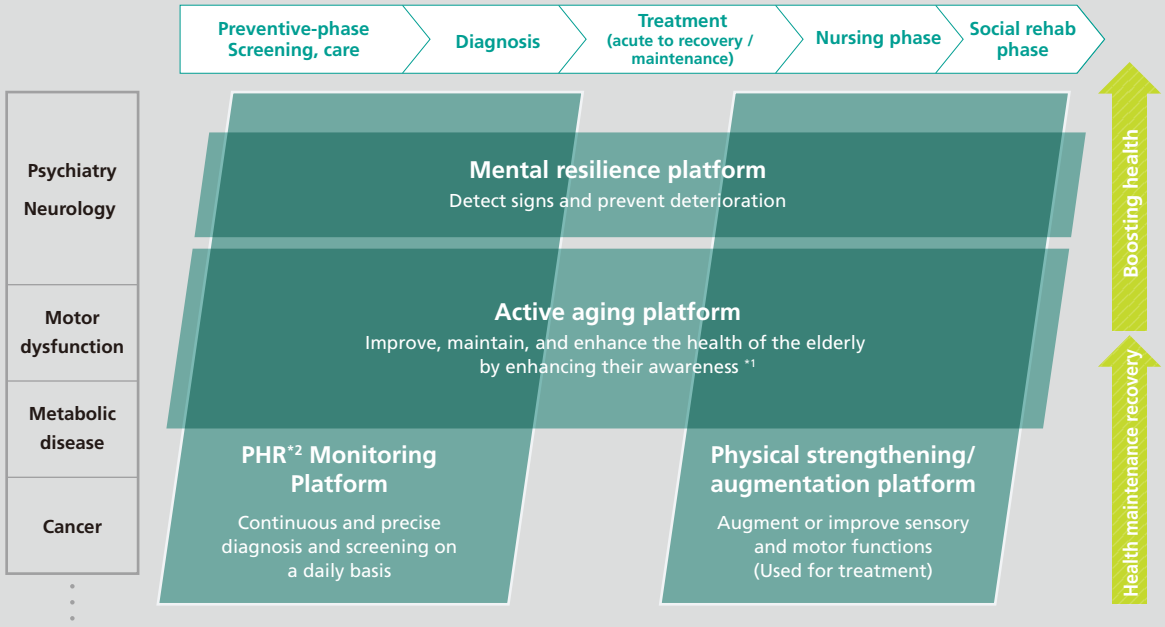
(Note) For China segment only

Basic Policy I

Establishment of growth engine

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 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).

Our Approach to the Frontier Business

Patient-driven

Flexible, personalized solutions that go beyond medication to improve access to care, offer additional options and diminish stigmas and isolation

Science-minded

Leveraging our expertise in developing medications that meaningfully enhance mental health and active aging

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
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Strategy 5: Launch frontier business

Basic Policy II

Solution-focused
Scouting for ideas, connecting the best scientific minds and collaborating on cutting-edge innovations to pioneer new frontiers in healthcare

Visionary
Redefining the relationship between pharma and total wellbeing to revolutionize supportive care through empowering and convenient choices

Global
Exploring and facilitating opportunities for exciting collaboration and inspiring business across the geographic border, starting from the U.S. Japan, and China

Major projects

Fiscal 2022 product launch schedule
- MELTz Hand Rehabilitation System: Certified under the general designation of "active extension/flexion/extension rotation exercise device"
  Manufacturer: MELTIN; Distributor: Sumitomo Pharma. Plan to start sales in 2022.
- Digital devices for relieving BPSD: Full-scale sales primarily by our partner (Aikomi, our associated company).
- VR contents for mental health: Sales primarily by our partner (BehaVR) (Profit share 50-50 with both companies)

Area	Program	Summary	Region	Development status	Partnering
Psychiatry Neurology	Digital devices for relieving BPSD	Tailor-made contents for stimulating five senses that digitally realize nonpharmacotherapy	Japan	In trial sale (non-medical device)	Aikomi Ltd., Sompo Japan Insurance Inc.
	VR contents for mental health wellness	VR program for the selfmanagement of mental health issues related to stress, worry and low mood. Users will set goals and objectives meaningful to them while they learn how to cope with negative situations encountered in their daily lives	U.S.	Product development (non-medical device)	BehaVR, Inc.
	Wearable EEG meter	Service for early detection of mental diseases by daily capture of the EEG profile with simple wearable EEG meter	Japan	Product development (medical device)	NeuroSky Co., Ltd.
	Smart device for hard of hearing people	Develop smart devices that display multiple utterances as subtitles as a new communication support tool for hard of hearing people	Japan	Product development (non-medical device)	Pixie Dust Technologies, Inc.
Motor dysfunction	MELTz Hand Rehabilitation System	Robotic neurorehabilitation device utilizing motion intention of patients with post-stroke hand/fingers paralysis from electromyogram for the patients	Japan	Certified (medical device)	MELTIN
Metabolic disease	Automated blood collection/ stabilization device	Blood collection device designed for low pain, long-term storage, and simple transportation for the self-management tool such as diabetes	Japan	Product development (medical device)	Drawbridge Health, Inc.