Long-Term Business Plan 2031

–Kaken Vision for Transformation–

May 2022

KAKEN PHARMACEUTICAL CO., LTD.

Agenda

Corporate Philosophy and Value Creation Story

Corporate Philosophy

KAKEN helps improve the quality of life of patients by serving as many people as possible to return smiles of happiness to their faces, through supplying superior pharmaceuticals.

INPUT

Financial capital
- Safe and sound financial position
- Equity ¥137,747 million (As of March 31, 2022)

Manufacturing capital
- Capital expenditures in new business and capacity expansion/renovation ¥3,510 million (Year ended March 31, 2022)

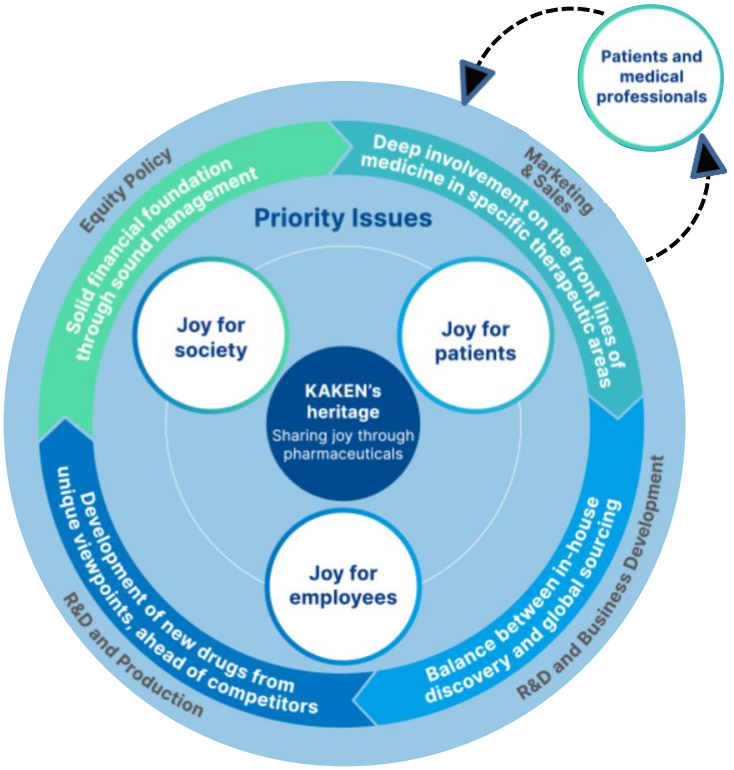
Intellectual capital
- R&D investment ¥8,420 million (Year ended March 31, 2022)
- Drug Research Center 2 locations (Kyoto and Shizuoka)

Natural capital
- CO_2 emissions 20,282 t-CO_2
- Electricity consumption 25,608 thousand kWh
- Water consumption (Shizuoka Site) 2,674 thousand m³

Social capital
- Main offices 8
- Sales offices 34

Human capital
- Number of Group employees 1,164 (As of March 31, 2022)

BUSINESS MODEL



OUTPUT

Innovative drugs, including products that are the first of their kind in Japan or the world

Dermatology


Clenafin


Ecclock


Fiblast

Orthopedics


Artz


Hernicore

Other Areas


Seprafilm


Regroth

OUTCOMES

- Innovative drugs that satisfy unmet medical needs
- Stable supply of quality pharmaceuticals with proven health economics
- Provision of proper pharmaceutical and related medical information
- Improved quality of life of patients and their family members
- Longer healthy life expectancy
- Rewarding workplaces for employees
- Stable and continuous returns to shareholders

Sustainability Management
- Our Mission and Process of Identifying Priority (Material) Issues

- Based on our mission *"deliver value to society and contribute to achieving a sustainable society by practicing its corporate philosophy", we* have identified priority (material) issues.

Our Mission	*Deliver value to society and contribute to achieving a sustainable society by practicing its corporate philosophy.*

Process of Identifying Priority (Material) Issues

【Identify】

To determine the priority issues to be addressed through KAKEN's business activities, the Corporate Planning & Coordination Department and the General Affairs Department first identified social issues taking into account, among other factors, the status of the Company's business, management plans, GRI Standards, and ISO 26000.

【Compile】

We identified and mapped social issues on two axes: "Relevance to KAKEN's business" and "Impact on stakeholders" in order to narrow issues down to those with a high degree of importance. From these, we compiled priority issues, their associated risks, opportunities and main initiatives, taking into account KAKEN's business philosophy.

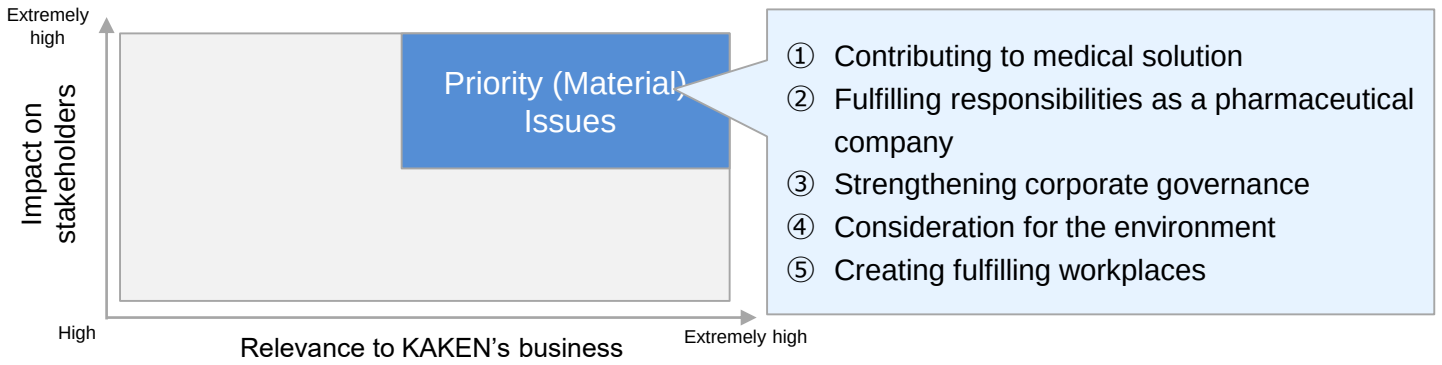
【Designation】

The items selected were deliberated by management and designated as priority issues for the KAKEN Group.

【Review】

These priority issues are reviewed in light of changes in the Company's operating environment, progress of initiatives, and stakeholder opinions collected through dialogue.

【Mapping of Priority (Material) Issues】



Sustainability Management - Main Initiatives to Address Priority (Material) Issues

We will address the following initiatives for the priority (material) issues.

Business Philosophy "Three Joys"	Priority (Material) Issues	Associated Risks and Opportunities (Risks: ▲, Opportunities: ○)	Main Initiatives	Related SDGs
"Joy for patients" We strive to create and supply efficacious drugs that satisfy the needs of patients and medical professionals.	❶ Contributing to medical solutions • Creation of innovative new drugs that satisfy unmet medical needs • Provision of pharmaceuticals with proven health economics • Partnerships with domestic and overseas companies and others	▲Insufficient development pipeline ▲Changes in healthcare policies and market trends ○ Fulfillment of unmet medical needs ○ Contribution to society and heightened Company presence through development of innovative drugs	• Focus management resources on research and development • Promote alliances with overseas companies and others (for in-licensing of products under development, out-licensing of in-house products, joint research and other purposes)	
	❷ Fulfilling responsibilities as a pharmaceutical company • Stable supply of high-quality pharmaceuticals with proven safety • Activities to provide accurate information • Intellectual property strategies	▲Decline in corporate value due to disruption in supply of pharmaceuticals ▲Impact of intellectual property risks on business ▲Suspension of sales due to inappropriate activities ○ Maximization of product value through stable supply and provision of useful information	• Maintain domestic and international standards for good manufacturing practice (GMP) • Contribute to better medical treatment by improving product value in ways such as generating evidence • Utilize digital tools and other means to establish efficient systems for delivering information • Global intellectual property strategies	
"Joy for society" We recognize our social responsibility as a pharmaceutical company, engage in all activities with high ethical standards, and aspire to earn society's trust.	❸ Strengthening corporate governance • Strengthening relationships with stakeholders • Promotion of compliance • Risk management to ensure business continuity	▲Decline in stakeholder trust ▲Disruption of supply chain ▲Increased risk of violations of laws and regulations, misconduct and other inappropriate actions ○ Earning stakeholder trust	• Strengthen governance framework • Appropriate and timely information disclosure and dialogue • Training and education in compliance, risk management, and relevant laws and regulations • Contribute to local communities (participation in activities such as local beautification and disaster relief support) • Develop/Update disaster and pandemic response plans	
	❹ Consideration for the environment • Proper management of waste and wastewater • Efficient use of water and other resources • Reduction of CO_2 emissions • Supply of eco-friendly agrochemicals	▲Disruption in production due to factors including depletion of water and other resources ▲Decline in public trust due to insufficient efforts ○ Cost reductions from energy conservation initiatives ○ Contribution to global food safety	• Roll out environmental management system • Maintain ISO 14001 certification (Shizuoka Site) • Continue CO_2 emission reduction initiatives • Research and development of eco-friendly agrochemicals	
"Joy for employees" Our objective is to become a company with vitality and presence whose employees enjoy and take pride in their work.	❺ Creating fulfilling workplaces • Generating and maintaining employment opportunities • Work-style reform and improved productivity • Employees' health, occupational safety and welfare • Diversity • Development of the next generation of human resources • Respect for human rights	▲Outflow of personnel ▲Labor issues ▲Decline in productivity ○ Corporate growth from increased employee fulfillment and motivation ○ Hiring and retention of talented personnel	• Work-style reform (including digitalization of work processes) • Appoint female directors • Enhance systems for employing people with disabilities and seniors • Help protect employees against disease and promote mental healthcare initiatives • Training programs, self-development support and discrimination/harassment prevention	

Review of Medium-Term Business Plan 2021 (1/2)
- Achievement of the Target KPIs and Progress in R&D Pipeline

- We revised the FY2021 targets of net sales and operating profit to ¥79.2 billion and ¥18.8 billion, respectively, due to the impact of COVID-19 pandemic. However, the results of FY2021, the final year of the plan, were ¥76.0 billion and ¥17.0 billion, respectively.
- With regard to the R&D pipeline during the period of the plan, we achieved the launch of Ecclock and application filed for KMW-1.

■ Achievement of the Target KPIs

	Original Target (Announced in May 2019)	Revised Target (Announced in May 2021)	Results of FY2021
Net Sales	¥94.5 billion	¥79.2 billion	¥76.0 billion
Operating Profit	¥25.0 billion	¥18.8 billion	¥17.0 billion
ROE	12% or more	—	7.0%

■ Progress in R&D Pipeline During the Period of the Plan

Legend ■ in-house drug discovery ■ Acquired through M&A

Stage*	Phase I	Phase II	Phase III	Application Filed	Launched
Product	**BBI-4000** (Primary palmoplantar hyperhidrosis) **KP-483** (Solid tumors) Preparing for clinical studies **NM26-2198** (Atopic dermatitis)	Acquired in Dec. 2021 **ART-001** (Refractory vascular malformations) Acquired in Dec. 2021 **ART-648** (Bullous pemphigoid)	**KAR** (Head lice)	Filed in Jun. 2021 **KMW-1** (Removal of burn eschar)	Launched in Nov. 2020 **Ecclock** (Primary axillary hyperhidrosis)

*As of May 2022. Including the preparation period for IND.

Review of Medium-Term Business Plan 2021 (2/2)
- Main Achievements and Unresolved Issues

- While we successfully expanded Clenafin into new overseas markets, certain issues remained unresolved, such as taking on the challenge of broader drug discovery research, accelerate overseas expansion, and continuous reinforcement of the management base.

■ Main Achievements

Maximized Product Value	Overseas expansion of Clenafin ✓ [Hong Kong/Macao] Main Life Corp. Ltd. (licensee) started distribution. ✓ [China] AIM (licensee) is to start local clinical development. ✓ [Europe] Concluded exclusive out-licensing and supply agreements in Europe with Almirall S.A.
	Overseas expansion of new products and additional indications ✓ Conducting Phase I study in Japan for additional indication of Ecclock for primary palmoplantar hyperhidrosis.
Stronger and More Efficient Marketing Base	✓ Reorganization of the Marketing and Sales Division into five branch offices and 34 sales offices and the introduction of digital promotion tools improved quality and efficiency of MR activities.
Higher Productivity through HR Development and Operational Transformation	✓ Work-style transformation, such as telecommuting and flextime; developed DX talent at individual divisions. ✓ Improved efficiency of operations in ways such as introducing remote meetings and paperless operations, as well as IT investment.

■ Unresolved Issues

Challenge for Broader Drug Discovery Research	✓ Expansion of the pipeline through in-house drug discovery, mainly in therapeutic areas where we have advantages. Taking on the challenge of drug discovery research in new therapeutics areas. ✓ Taking on the challenge of peptides and other new modalities, beyond small molecules. ✓ Taking on the challenge of new technologies, such as regenerative medicine.
Accelerate Overseas Expansion	✓ Expansion of Fiblast in countries other than South Korea and overseas expansion of Regroth is not yet available. ✓ Need to accelerate overseas expansion by formulating strategy for each product and region.
Continuous Reinforcement of the Management Base	✓ [HR] Continuously updating work-style transformation and human resource development by staying current with the time. ✓ [DX] Decision to be made for the intended use and tools to accelerate R&D transformation. ✓ [Manufacturing] Investment and transform employee mindset for a higher-quality and more reliable manufacturing system.

Changes in Company's Business Environment and Recognized Long-Term Issues

- Due to the aging of Japanese society and tighter public finance for medical care, the business environment surrounding the prescription pharmaceutical industry is changing dramatically.

Business Environment

External Environment	✓ Aging of the society makes longer healthy life expectancy even more important ✓ Increased importance of ESG/SDGs
Market Forecast	✓ [Japan] Shrinking market size due to drug price revisions, decreasing population and generic penetration ✓ [Global] Growth in specialty areas and new emerging economies
Shifts in Healthcare Paradigm	✓ Medical care is broadening not only from diagnosis and treatment, but also to prophylaxis and prognosis as well ✓ More customized medical care for each patient or subpopulation by actively using genetic information and other healthcare data
Trends in In-House Drug Discovery	✓ From lifestyle diseases to unmet medical needs ✓ From small molecules to biopharmaceuticals and regenerative medicine ✓ Increased difficulty and cost in development

KAKEN PHARMACEUTICAL

Our Long-Term Issues

R&D	✓ Achieve higher level of successful product launches ✓ Further strengthen expansion of pipeline ✓ Take on the challenge of global research and development
Overseas Expansion	✓ Strengthen our own overseas expansion, considering the shrinking domestic market
Management Base	✓ Develop human resources, capable of addressing transformations ✓ DX ✓ Effective capital investment and cost reduction

Vision and Strategy Toward FY2031

Vision

1. A company that contributes to longer healthy life expectancy by developing and supplying innovative new drugs in a speedy manner
2. A research-based pharmaceutical company with a global presence, primarily in the areas of dermatology and orthopedics

Strategy for Achieving the Vision

"3Xs"

- Three Transformations -

- 1st X **R&D** Transformation
- 2nd X **Overseas Expansion** Transformation
- 3rd X **Management Base** Transformation

Strategy for Long-Term Business Plan 2031

“3Xs” - Three Transformations -

1st X	**R&D** Transformation	1. Utilize KAKEN’s own research base 2. Expand into new therapeutic areas 3. Take on the challenge of new modalities 4. Actively invest in research and development
2nd X	**Overseas Expansion** Transformation	1. Enhance line-up of global products from in-house drug discovery and in-licensing of products already commercialized or under development 2. Maximize the value of global products through our own development and commercialization overseas
3rd X	**Management Base** Transformation	1. Develop human resources capable of pursuing transformation as professionals and improve the working environment 2. Create a corporate culture capable of continuous transformation by utilizing data and digital technology 3. Maximize product value and establish reliable and high-quality manufacturing capabilities from the viewpoint of “patients first”

Strategy for Long-Term Business Plan 2031

“3Xs”

1st X R&D Transformation

Vision and Overview of R&D Strategy

VISION

Continuously launch innovative, world-class drugs in our three priority fields of drug discovery

POLICY

- Utilize KAKEN's own research base
- Expand into new therapeutic areas
- Take on the challenge of new modalities
- Actively invest in research and development

PRIORITY MEASURES

(1) Improve launch probability

- Utilize process innovation and achieve higher efficiency to shorten length of research and development
- Diversify approaches to increase success rates

(2) Expand pipeline

- Increase the number of licensed products
- Use external resources in early-stage development
- Seek new indications and drug repositioning

(3) Address new needs and overseas expansion

- Identify original targets that address unmet medical needs
- Promote research and development aimed at overseas clinical development

(4) Take on challenge in new fields

- Select and work on modalities and take on the challenge of regenerative medicine
- Consider the introduction of digital therapeutics in orthopedics and dermatology

Allocate ¥200 billion for R&D investment over the 10 years of the plan

TARGET

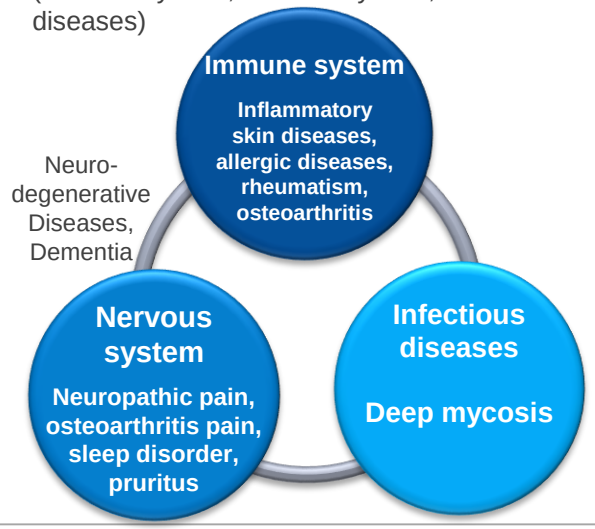
- Secure a development pipeline capable of launching eight new products over the 10 years of the plan (maintain at least six projects in Phase I or later phases at any given time)
- Secure at least one new licensed products or new marketing alliance every year (10 products over the 10 years of the plan, including five for overseas development)

Basic R&D Policies

▶ For R&D, we will work on each measure based on the following four basic policies.

Utilize KAKEN's Own Research Base

✓ Strengthen in-house research base mainly in the three priority fields of drug discovery (immune system, nervous system, infectious diseases)



Expand into New Therapeutic Areas

✓ Expand into new therapeutic areas where we have advantages, based on unmet medical needs

Therapeutic areas where we have advantages

Orthopedics	Dermatology	Other
Artz Hernicore	Clenafin Ecclock Fiblast	Seprafilm Regroth

New therapeutic areas
- Diseases with unmet medical needs at 10 years in the future
- Rare diseases

Take on the Challenge of New Modalities

✓ Enable approaches to drug discovery targets that could not be achieved with small molecule drugs

Areas to take on challenges in research and development

Small molecule drugs

- Next-generation antibody
- Peptide
- Nucleic acid medicine, etc.

Actively Invest in Research and Development

✓ Allocate ¥200 billion for R&D investment (including ¥80 billion for M&A and in-licensing to expand pipeline) over the 10 years of the plan

✓ Cooperate with external organizations from the early stage of research and development
- Drug discovery seeds exploration: Utilize academia, venture consortiums, and others
- Joint research/development, in-licensing: Collaboration with domestic and overseas pharmaceutical related companies, M&A, and other entities

Background to the Priority Measures

	Current Status	Issues	Priority Measures
① **Improve Launch Probability**	➢ Clenafin, a in-house discovery product, has grown into a global product ➢ The hurdle for revolutionary drug development is very high and time consuming	➢ Shortening of the R&D period ➢ Improvement in success certainty in each stage ➢ Early obtainment and improving efficiency of PoC*	➢ Utilize process innovation and achieve higher efficiency to shorten the length of research and development ➢ Diversify approaches to increase success rates
② **Expand Pipeline**	➢ Difficult to acquire enough pipeline only with in-house discovered products ➢ In-license of developing products in a late stage ➢ Expansion of pipeline through M&A	➢ Building sufficient pipeline for continuous launch ➢ Improvement in R&D projects	➢ Increase number of licensed products ➢ Use external resources in early-stage development ➢ Seek new indications and drug repositioning
③ **Address New Needs and Overseas Expansion**	➢ Decrease in unmet medical needs ➢ Shrinking domestic market, suppression of drug prices ➢ Conducting joint development with overseas companies and multinational clinical trials ➢ Overseas expansion of Clenafin	➢ Finding potential unmet medical needs and materializing the means of solution ➢ In-house initiative on developing global products	➢ Identify original targets that address unmet medical needs ➢ Promote research and development aimed at overseas clinical development
④ **Take on Challenge in New Fields**	➢ Accelerating the initiatives toward longer healthy life expectancy ➢ Diverse needs toward medical care ➢ Expansion of the means of treatment other than pharmaceuticals	➢ Finding patient needs and providing specific means of solution ➢ Expanding treatment options for patients	➢ Select and work on modalities and take on the challenge of regenerative medicine ➢ Consider the introduction of digital therapeutics in orthopedics and dermatology

* PoC : Proof of Concept

Measure (1) Improve Launch Probability

Priority Measures Toward 2031

- Utilize process innovation and achieve higher efficiency to shorten length of research and development
  - Innovate drug discovery research and clinical development processes using AI and RWD*
  - Improve efficiency by actively utilizing external technologies and resources
  - Improve efficiency in clinical studies through virtual clinical trials
- Diversify approaches to increase success rates
  - Expand into various modalities
  - Promote translational research and early-stage clinical studies

Progress as of the end of FY2021	Goals in FY2026	Goals in FY2031
➢ Start drug discovery of next-generation antibody in addition to small molecule drugs ➢ Examine drug discovery using AI and biobank ➢ Examine the efficiency in acquisition and shortening the period of PoC	➢ Try new processes in each project and confirm the effect of acceleration of NDA period ➢ Start projects planned with new drug discovery methods and/or modalities (Discover two projects/year) ➢ Judgeable PoC in the early development stage	➢ Shorten the period from drug discovery to NDA by two-thirds ➢ Increase the launch frequency of products from in-house drug discovery by three times

* RWD : Real World Data

Measure (2) Expand Pipeline

Priority Measures Toward 2031

- Increase the number of licensed products
  - Widen the range of in-license exploration mainly in the three priority areas (expansion of modalities, working on rare diseases)
  - Diversify the opportunity of in-licensing (seek opportunities in M&A, establishment of CVC* fund, investment in fund)
- Use external resources in early-stage development
  - Joint research and development with drug discovery biotech companies and in-licensing of development products at the early stage
- Seek new indications and drug repositioning

Progress as of the end of FY2021	Goals in FY2026	Goals in FY2031
➢ In-license late-stage development products, acquisition of a company with pre-PoC products through M&A ➢ Joint research of external drug seeds, utilizing external research institutions ➢ Additional indications of approved drugs	➢ Six projects in Phase I or later stage (including in-licensed late-stage development products) ➢ Additional indications of products under development	➢ More than six in-house discovered drug products in Phase I or later stage (including in-licensed pre-PoC products) ➢ In-license (or sales alliance) late-stage development products every year

* CVC : Corporate Venture Capital

Products under Development

[In-House Discovered and In-Licensed Drugs]

Product	Development Stage*	Therapeutic Area	Planned Indication	Modality
KMW-1	Filed	Plastic Surgery, Emergency Department	removal of burn eschar	Protein
KAR	P3	Dermatology	Head lice	Small molecule
ART-001	P2	Plastic Surgery, Pediatrics, Dermatology	Refractory vascular malformations	Small molecule
ART-648	P2	Dermatology	Bullous pemphigoid	Small molecule
BBI-4000	P1	Dermatology	Primary palmoplantar hyperhidrosis	Small molecule
KP-483	P1	-	Solid tumors (immune-oncology)	Small molecule
NM26-2198	P1	Dermatology	Atopic dermatitis	Antibody

*As of May 2022. Including the preparation period for IND.

[Out-Licensed Overseas]

Product	Out-Licensed to	Indication	Modality
Clenafin	China (preparing for clinical study) Europe (preparing for NDA)	Onychomycosis	Small molecule

Major Discovery Research and Challenge in New Areas

[Drug Discovery of Prescription Pharmaceuticals]

Drug Discovery Research Area	Mode of Action	Modality
Nervous system	Ion channel	Small molecule New modalities (peptides, antibodies, etc.)
	Modulator of G protein-coupled receptor	
Immune system	Suppressor of cytokine signal	
	Ion channel	
Infectious diseases	Inhibition of fungus specific target	

[Challenge in New Areas]

Target Areas	Therapeutic Areas	Modalities and Implements
Regenerative medicine	Orthopedics and others	Cells, peptides, and others
Digital health (Medical device)	Dermatology, Orthopedics	Medical devices, apps, and others

Measure (3) Address New Needs and Overseas Expansion

Priority Measures Toward 2031

- Identify original targets that address unmet medical needs
  - Identify latent medical needs for 15 years in the future, using big data and other tools
  - Define Kaken-specific targets
- Promote research and development aimed at overseas clinical development

Progress as of the end of FY2021	Goals in FY2026	Goals in FY2031
➢ Explore the discovery methods of new targets (AI and etc.) ➢ Promote joint development with overseas partners ➢ In-license products with potential expansion to overseas	➢ Propose and start drug discovery projects of original targets using big data and others ➢ Build non-clinical data assuming global IND*, and secure the supply system of investigational drugs for overseas ➢ Conduct in-house global clinical study using CRO**	➢ Promote drug discovery on our original target ➢ Promote in-house global development

* IND : Investigational New Data

** CRO : Contract Research Organization

Measure (4) Take on Challenges in New Fields

Priority Measures Toward 2031

- Select and exert research and development of modalities to realize regenerative medicine through collaboration with specialty companies or in-licensing and M&A
  - Cell (mesenchymal stem cells, iPS cells, etc.)
  - Exosomes
  - Other regeneration inducer substances (peptides etc.)
- Consider the digital therapeutics in orthopedics and dermatology (including medical devices) through collaboration with specialty companies or in-licensing and M&A
  - OA : Management and improvement of disease condition through walking, posture, and amount of daily activities, etc.
  - Pain : Management of pain with apps
  - Dermatitis : Photographic images of affected areas; adherence management

Progress as of the end of FY2021	Goals in FY2026	Goals in FY2031
➢ Apply bFGF to cell culture reagent ➢ Consider marketing alliance for regenerative medicine products, etc. ➢ Consider apps to improve medication adherence	➢ Start and promote joint development project for regenerative medicine products with start-up companies ➢ Start and promote joint development projects for digital health products with start-up companies ➢ Synergies on advantageous therapeutic areas and existing products	➢ Develop and launch of regenerative medicine products ➢ Develop and launch of digital health products

Strategy for Long-Term Business Plan 2031

“3Xs”

2nd X Overseas Expansion Transformation

Vision and Overview of Overseas Expansion Strategy

VISION

Increase the overseas sales ratio and consolidate our position as an R&D-driven company with mainstay products in the areas of dermatology and orthopedics

POLICY

- Enhance line-up of global products from in-house drug discovery and in-licensing of products already commercialized or under development
- Maximize the value of global products through our own development and commercialization overseas

PRIORITY MEASURES

(1) Expand global products

- Accelerate overseas expansion of existing global products
- Secure and expand new global products

(2) Establish our own overseas development capabilities

- Create our own overseas clinical development structure and commence operation
- Consider establishment of an overseas development center

(3) Establish global manufacturing and commercialization structure

- Establish manufacturing system for global products
- Conduct a study on establishing our own overseas sales and marketing operations

TARGET

- For pharmaceuticals, overseas sales ratio of 25% or higher

Global Products

Existing global products
Clenafin, Ecclock, Regroth, Fiblast

New global products
KP-483, ART-001, ART-648, NM26-2198,
products from in-house drug discovery, new licensed products

Background of Priority Measures

	Current Initiatives	Issues	Priority Measures
Expand Global Products	➢ Overseas expansion of Clenafin • Our partner companies have launched in North America, South Korea, Taiwan, Hong Kong, and Macao ➢ Out-license of existing global products • Seeking new out-license opportunities for existing global products	➢ Need to approach and expand the regions where existing global products have not been launched yet. ➢ For new global products, need to formulate the overseas expansion strategy by each product and region, and accelerate the overseas expansion ➢ Need to increase the number of global products	➢ Accelerate overseas expansion of existing global products ➢ Secure and expand new global products
Establish Our Own Overseas Development Capabilities	➢ Have experience in conducting multinational clinical trials in Japan and North America ➢ Preparing for MAH* status in China	➢ Need to establish our own organization/system for developing new global products overseas (including overseas regulatory affairs) ➢ Lack of experience in our own overseas development (including overseas regulatory affairs)	➢ Create our own overseas clinical development structure and commence operations ➢ Consider establishment of an overseas development center
Establish Global Manufacturing and Commercialization Structure	➢ Manufacture Clenafin for overseas markets • Manufacture finished product for Taiwan and Hong Kong, and intermediate product for South Korea ➢ Manufacture Fiblast for overseas markets • Manufacture intermediate product for South Korea ➢ Our partner companies distribute Kaken's products overseas.	➢ Need to comply with regulatory affairs in each country for global products • Since Kaken is incapable of manufacturing finished product that comply with the regulations in each country, our partner companies need to carry out part of manufacturing process ➢ Since the overseas sales of global products are entrusted to our partner companies, profitability is low.	➢ Establish manufacturing system for global products ➢ Conduct a study on establishing our own overseas sales and marketing operations

* MAH : Marketing Authorization Holder

Measure (1) Expand Global Products

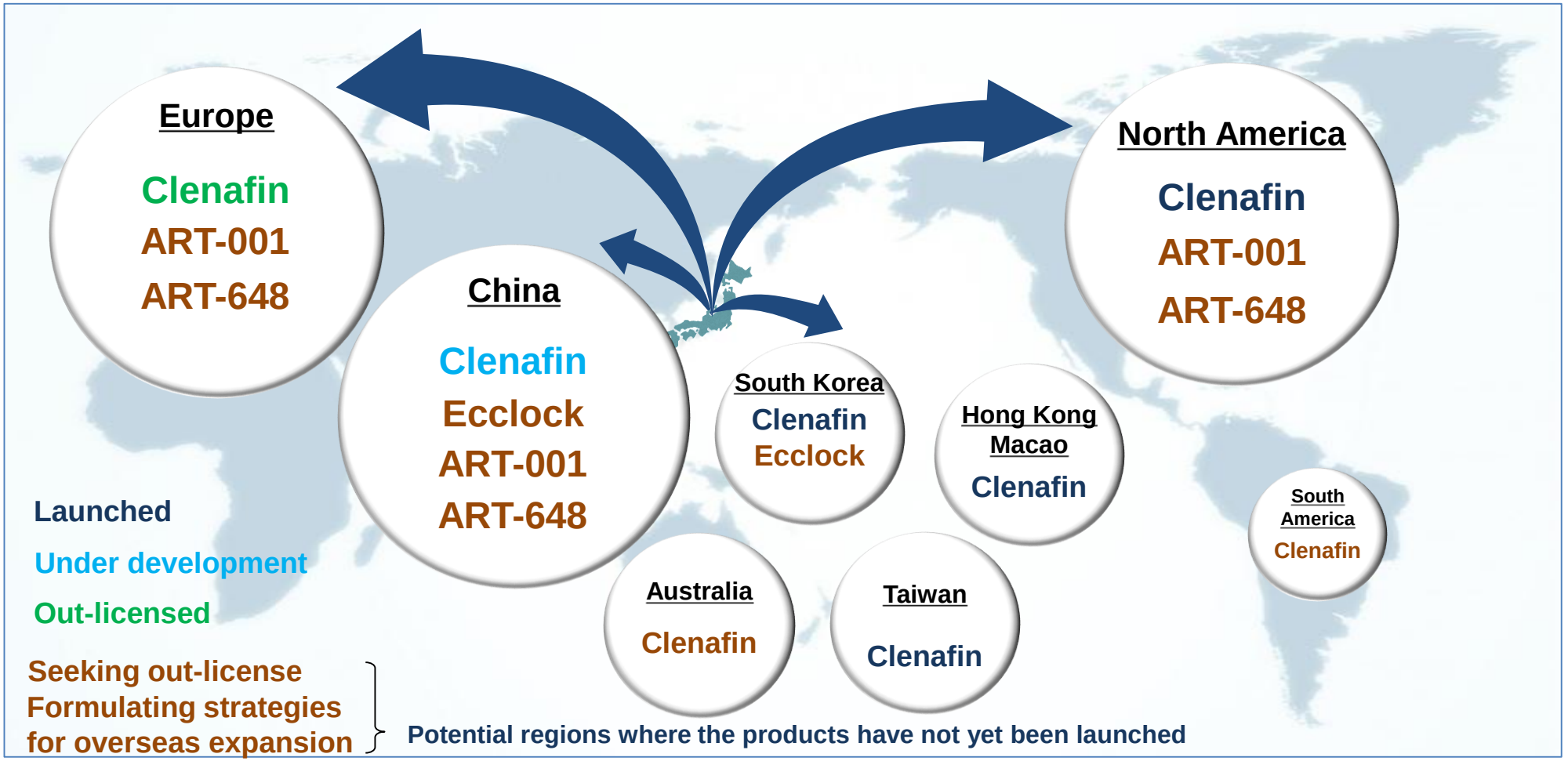
Priority Measures Toward 2031

- Accelerate overseas expansion of existing global products
  - Promote out-licensing activities for existing global products to the regions where such products have not been launched yet
  - Promote out-licensing activities for new global products
- ➢ Secure and expand new global products
  - Obtain the global right when executing license agreement
  - In-license five or more of global products over the 10 years of the plan
  - Conduct a study on M&A, establishment of CVC fund (internal fund) and investment in the fund

Progress as of the end of FY2021	Goals in FY2026	Goals in FY2031
➢ Overseas expansion of Clenafin • Our partner companies have launched in North America, South Korea, Taiwan, Hong Kong, and Macao • Our partner company is developing in China • Completed out-license in Europe • Seeking out-license opportunity in South America ➢ Out-license of other global products • Seeking new out-license opportunities – Ecclock, Regroth, Fiblast • Formulating the strategy for overseas expansion – KP-483, ART-001, ART-648, NM26-2198	➢ Overseas expansion of existing global products • Launch Clenafin in China and Europe • Out-license and launch Ecclock in South Korea • Out-license Ecclock in the regions other than South Korea ➢ Formulate the strategy for overseas expansion of new global products • Formulate the strategy for overseas expansion for KP-483, ART-001, ART-648, and NM26-2198 ➢ In-license three new global products	➢ Expand the region where existing global products have been launched ➢ For new global products, formulate the overseas expansion strategy by each product and region, and start deployment ➢ Improve brand power by launching new products and obtain the global right when executing license agreement ➢ Secure three to five global products in place constantly

Progress of Overseas Expansion by Product

- Seeking new out-license opportunity of Clenafin which has already been launched in North America, South Korea, Hong Kong, Macao, and Taiwan, and formulating the strategies for out-license and overseas expansion of the developing products.
- Work more aggressively on overseas expansion activities through enhancing global products



Measure (2) Establish our Own Overseas Development Capabilities

Priority Measures Toward 2031

- Establish our own organization/system for overseas clinical development and commence operation
  - Promote the establishment of our own organization/system for conducting clinical development by using global CRO
  - Promote the establishment of the organization/system that can comply with regulations of each country
- Consider to open overseas offices for development of global products
  - Consider opening of overseas offices for development in the U.S. and/or other countries

Progress as of the end of FY2021	Goals in FY2026	Goals in FY2031
➢ Multinational clinical trials • Have experience in conducting multinational clinical trials in Japan and North America ➢ Preparing for MAH status in China	➢ Establish our own organization/system for conducting clinical development in the U.S. and China from Japan using global CRO • Main target products (region) – Ecclock (China) – ART-001 (US) ➢ Determine the possibility of opening an office to develop global products in the U.S.	➢ Establish our own organization/system for conducting clinical development from Japan using global CRO (including co-development) ➢ Establish the organization/system that can comply with regulations of each country

Measure (3) Establish Global Manufacturing and Commercialization Structure

Priority Measures Toward 2031

- Establish manufacturing system for global products
  - Consider in-house manufacturing system that complies with the regulations of each country
- Consider to establish our own overseas sales organization
  - Consider our own direct overseas sales at any opportunity

Progress as of the end of FY2021	Goals in FY2026	Goals in FY2031
➢ Manufacture Clenafin for overseas markets • Finished product (Taiwan, Hong Kong) • Intermediate product (South Korea) • Planning to manufacture intermediate product (China, Europe) ➢ Manufacture Fiblast for overseas markets • Intermediate product (South Korea) ➢ Our partner companies are distributing Kaken's products overseas.	➢ Start in-house manufacturing of Ecclock for overseas markets	➢ Establish the manufacturing system of finished products for overseas markets ➢ Consider to establish our own overseas sales and marketing operations

Strategy for Long-Term Business Plan 2031

“3Xs”

3rd X Management Base Transformation

Vision and Overview of the Strategy for Management Base

VISION

Increase corporate value by establishing a strong organizational base that can flexibly respond to change and by improving operational efficiency.

POLICY

Human Resource Strategy	• Develop talent who challenge themselves as professionals and pursue transformation • Increase employee engagement by establishing an optimal human resource management system and the working environment
DX Strategy	• Optimize research and development and the value chain • Foster a corporate culture of continual transformation using data and digital technologies
Production Strategy	• Maximize product value from the patient-first perspective • Establish a manufacturing system for stable and continuous supply of high-quality pharmaceuticals

Human Resource Strategy – Basic Policy and Priority Measures

Basic Policy

- Develop talent who challenge themselves as professionals and pursue transformation
- Increase employee engagement by establishing an optimal human resource management system and the working environment

Priority Measures

(1) Foster a corporate culture and develop talent that generates innovative challenges

- Foster a corporate culture that encourages employees to take on challenges
- Develop employees with distinctive capabilities as professionals (Employees who think for themselves, take action, and get results)
- Develop and recruit digital talent who are suitable for the promotion of DX
- Develop and recruit global-minded talent to reinforce overseas expansion
- Reinforce the education and training system

(2) Pursue a better work-style system and working environment that support the growth of employees

- Transform the human resource management and work-style system and improve the working environment
- Promote diversity management

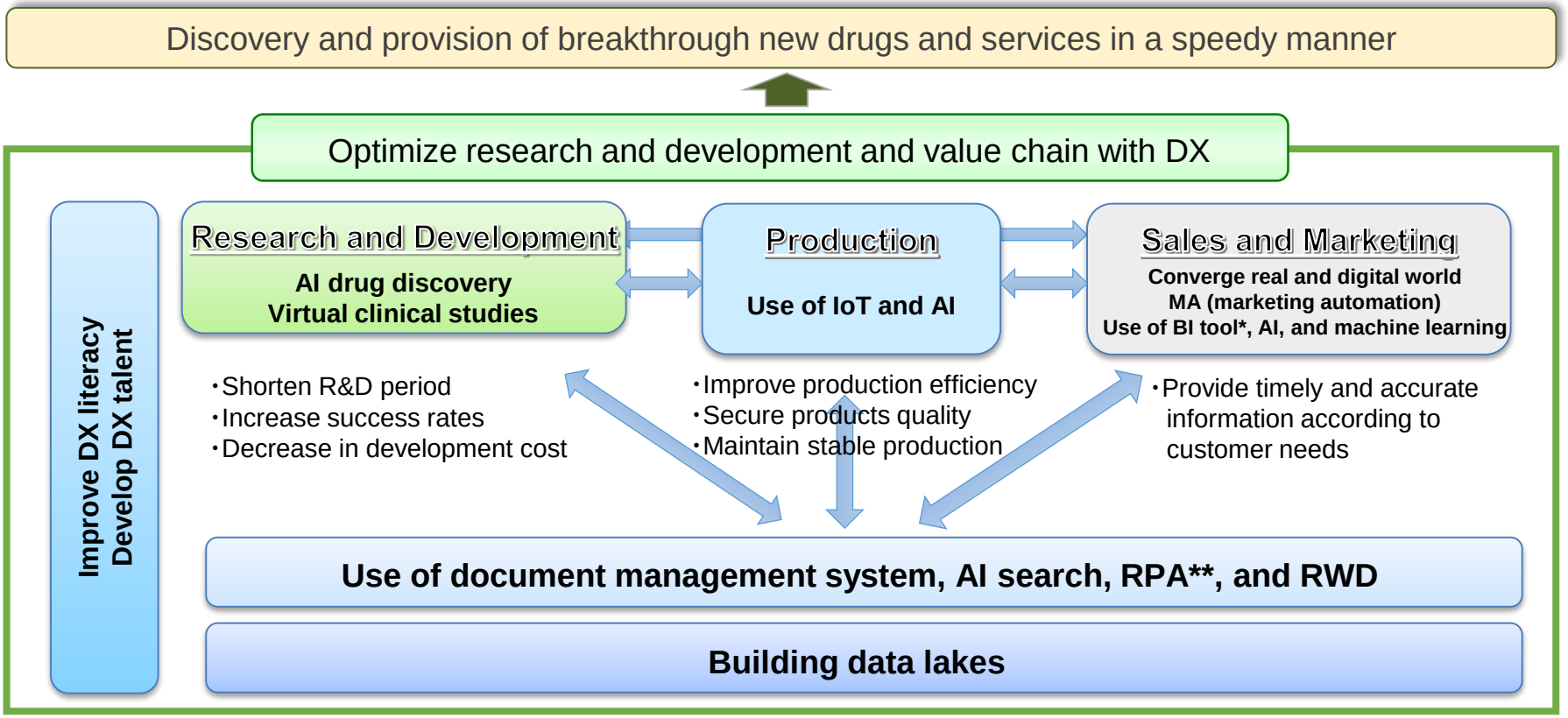
(3) Develop MRs who can flexibly respond to the changing times through convergence of the real and digital worlds

- Develop MRs with expertise equivalent to an MSL* in diseases we are focusing on as well as in products
- Optimize medical information provision based on data analysis, and make use of multiple communication channels
- Develop ability to plan and execute as a community healthcare partner based on a patient-first perspective

* MSL : Medical Science Liaison

DX Strategy (1/2) – Basic Policy and Priority Measures

Basic Policy	• Optimize research and development and the value chain • Foster a corporate culture of continual transformation using data and digital technologies



* BI tool : Business Intelligence tool

** RPA: Robotic Process Automation

DX Strategy (2/2) – Basic Policy and Priority Measures

Priority Measures

(1) Establish a growth foundation through process innovation of research and development

- Grasp unmet medical needs using RWD
- Cooperate with venture companies to introduce AI drug discovery and analysis tools
- Find seeds through research paper search using natural language analysis AI

(2) Optimize the value chain

- Improve efficiency of clinical studies using virtual clinical trials
- Transform operation processes using RPA, AI, and IoT
- Improve efficiency of medical information provision process using CRM* and MA**
- Sophisticate information provision using AI analysis and other analysis tools (improve probability and quality)

(3) Improve DX literacy and develop DX talent (implement in the human resource strategy)

- Develop DX talent and retain leaders with digital skills and mind
- Provide opportunities for learning DX (through seminar, e-learning, and correspondence courses)

* CRM : Customer Relationship Management

** MA: Marketing Automation

Production Strategy – Basic Policy and Priority Measures

Basic Policy	• Maximize product value from the patient-first perspective • Establish a manufacturing system for stable and continuous supply of high-quality pharmaceuticals
Priority Measures	**(1) Reinforce the production and quality assurance system from the patient-first perspective** • Build a solider manufacturing system by continuous investment • Stable procurement of raw materials and containers at good quality and appropriate prices by reinforcing the supply chain system • Improve credibility of data through linkage of the systems of manufacturing management, quality control, and document control • Improve formulation for better patients satisfaction **(2) Optimize manufacturing operations and strengthen cost awareness** • Optimize in-house production and outsourcing looking at the mid- to long-term demand • Introduce a new manufacturing method, such as continuous production method, aiming at reducing human errors and manufacturing costs • Manufacture products using digital technologies, improve efficiency of, and standardize quality control operations • Visualize and improve the costs using the cost management system

Strategy for Other Segment
– Agrochemicals Business –

Agrochemicals Business Strategy

VISION

Contribute to global food production by providing eco-friendly agrochemicals products

POLICY

- Maximize business value with polyoxins, natural substance derived from fermentation process using microorganisms, the key product of the growth strategy

PRIORITY MEASURES

(1) Growth in North America and new markets

- Strongly promote polyoxins in the organic crops market by leveraging the organic certification obtained in the US
- Promote polyoxins in the markets where registration was obtained recently (Australia, New Zealand, Chile, and India)

(2) Growth by entering into the EU market

- Anticipate the Import Tolerance we plan to submit to the EU to be approved by 2025, boosting polyoxins use in the crops exported for EU consumers
- Obtain registration for plant protection products in 2027, to enter the EU market

(3) Growth in Japan by promoting polyoxins use

- Promote polyoxins in the eco-friendly and sustainable agriculture market and contribute to improvement in crop productivity

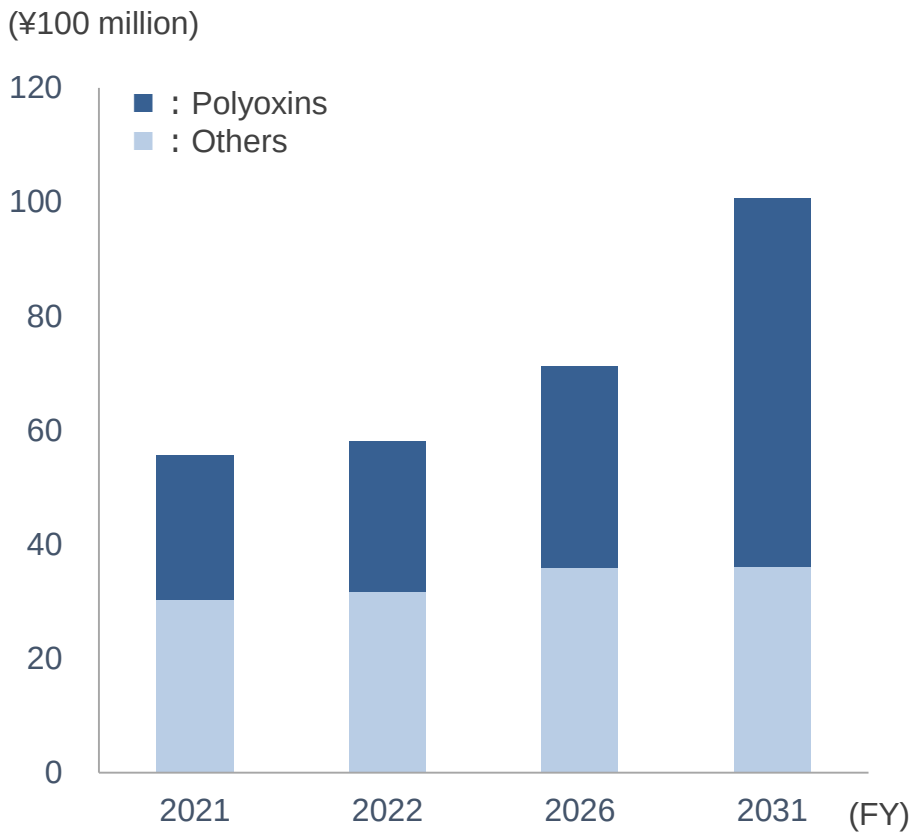
TARGET

- Targeting the net sales of ¥10 billion in the entire agrochemicals business mainly with polyoxins

Target Goals of Agrochemicals Business

- Reinforce overseas development and promotion of the use in Japan of polyoxins as the key product of the agrochemicals business growth strategy and aim to achieve the net sales of ¥10 billion in the entire agrochemicals business by FY2031

Net Sales Target of Agrochemicals Business



Growth Strategy for Polyoxins

	Measures	Target Region
2020	• Obtained the certificate of organic materials (OMRI* certificate) from USDA Organic Program	
2021	• Food Safety Commission of Japan, Cabinet Office, assessed ADI**	
2025 (plan)	• Approval of Import Tolerance (IT) we submit	
2027 (plan)	• Obtain registration for plant protection product	

*OMRI: Organic Material Review Institute supports organic farming and review agricultural materials, such as fertilizer, pest control for use in certified organic production and processing.

**ADI: Acceptable Daily Intake is defined as an estimate of the amount of substance in food, expressed on a bodyweight basis that can be ingested on a daily basis over a lifetime without appreciable risk to health.

Government Actions Related to Agriculture

- To solve the global issue of the sustainability in food systems, governments announced sustainable agricultural policy to reduce the use and risk of the chemical pesticide and to facilitate organic farming.

Region	Details of the Policy		
	Policy	Announced	Details
 USA	Agriculture Innovation Agenda	Feb. 2020	✓ The US Department of Agriculture (USDA) announced the goals of increasing productivity by 40% and reducing the environmental load in the agricultural segment by 50% by 2050 through positive use of innovation. ✓ The US announced a policy in which soil health and carbon storage in agriculture would be reinforced by 2050, and the US would achieve a net reduction of the current carbon footprint in the agricultural segment.
 EU	Farm to Fork Strategy (From farms to tables)	May 2020	✓ The European Commission adopted the strategy in which the food system from production to consumption would become fair and environmentally friendly in a healthy way as part of European Green Deal. ✓ Reduce the use of chemical pesticides and their risk by 50% by 2030 ✓ Increase the organic agriculture farm area by at least 25% by 2030
 Japan	Green Food System Strategy	May 2021	✓ The Ministry of Agriculture, Forestry and Fisheries formulated the strategy to balance between the increase in productivity of food and agriculture, forestry, and fishery and the sustainability through innovation. ✓ Reduce use amount (risk conversion) of chemical pesticides by 50% through conversion to low-risk agriculture by 2050, establish and spread of integrated pest management, and develop new agricultural chemicals, etc. to replace with conventional pesticides containing neonicotinoid. ✓ Increase percentage of organic agriculture farming area by 25% by 2050

Target KPIs of Long-Term Business Plan 2031

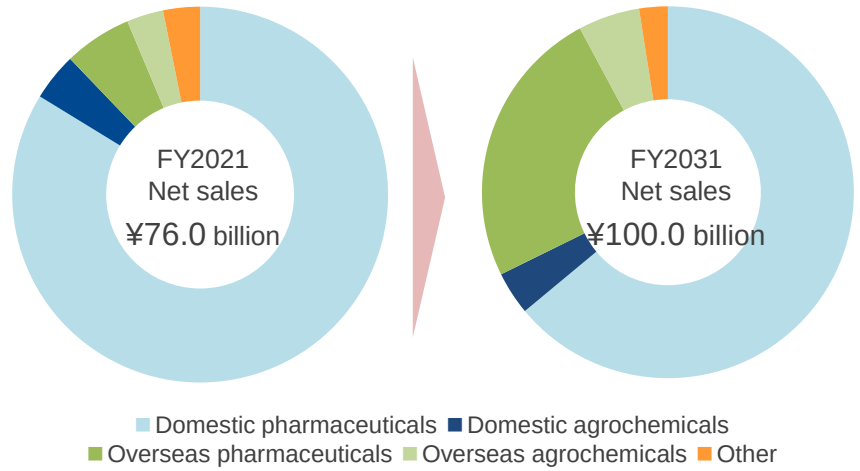
Target KPIs of Long-Term Business Plan 2031

■ Target KPIs

	FY2021 Result	FY2026	FY2031
Net Sales	**¥76.0 billion**	**¥80.0 billion**	**¥100.0 billion**
Operating Profit	**¥17.0 billion**	**¥18.0 billion**	**¥28.5 billion**
ROE	**7.0%**	**8%** or higher	**10%** or higher
Overseas Sales Ratio *	**9.1%**	**10%** or higher	**30%** or higher

* Total for pharmaceuticals and agrochemicals.

■ Targeted Change in Sales Breakdown



■ Investment and Shareholder Return Policy

Strategic Investment	◆ ¥200 billion or more over the 10 years of the plan
Shareholder Return	◆ Continuous/Stable dividends ◆ Flexible share buybacks

Notes about the Future Forecasts

- The performance forecasts described in this material are rational based on the information currently available and have been determined by the Company as reasonable.
- Considerable financial investment and a long development time are required before a new drug is launched. The Company carefully develop new drugs by confirming their efficacy and safety. There is a possibility that their development may be discontinued before completion, in such case where anticipated efficacy has not been proven or safety issues have been identified.
- The “Products under Development” is based on the current development plans. The status may change depending on their progress.
- The information about pharmaceutical products (including those under development) included in this material is not intended as an advertisement or medical advice.