Keidanren
Policy & Action

# Key Initiatives for Achieving Biotechnological Transformation (BX)

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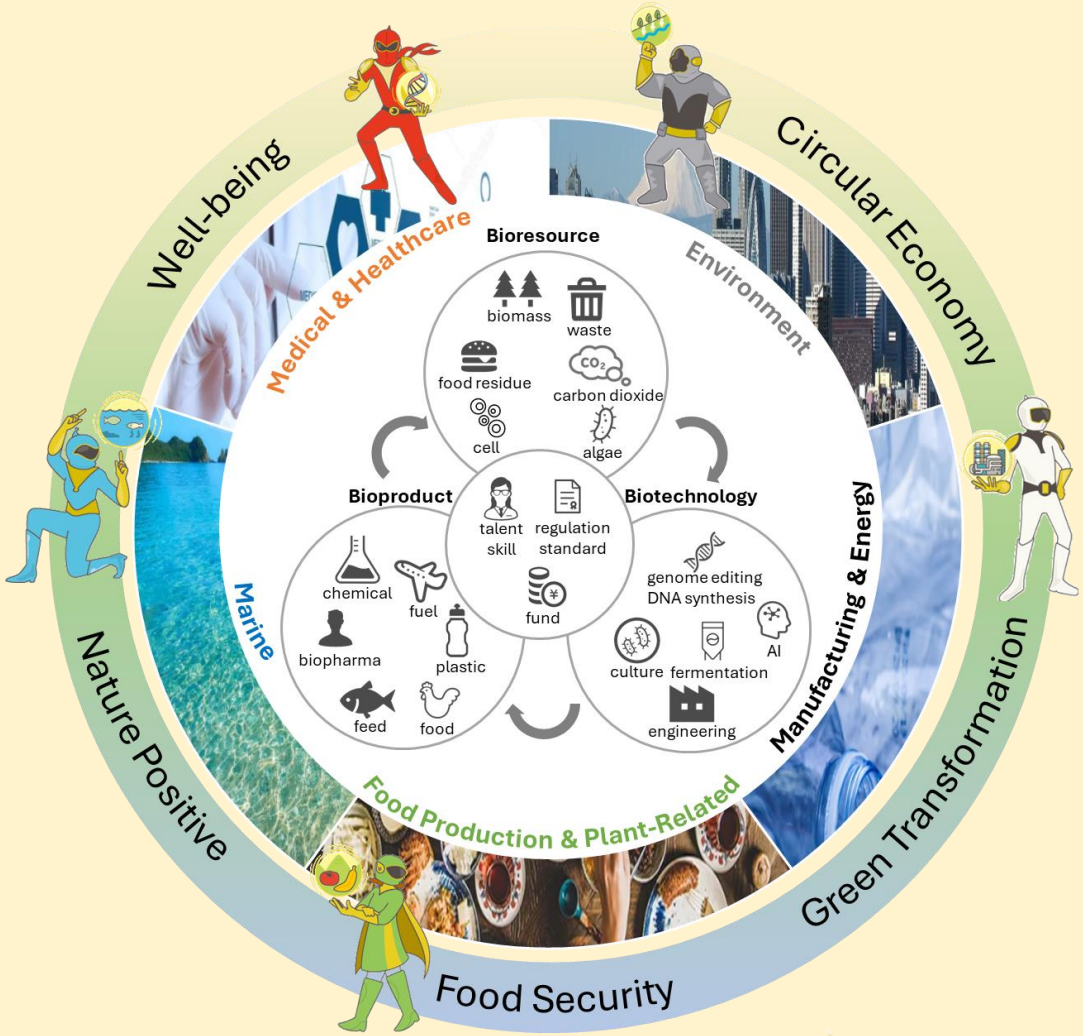
**KEIDANREN**

# Contents

# Ⅰ. Introduction

- The bioeconomy refers to a circular economy that contributes to solving societal issues such as decarbonization and food security.
- Building on Keidanren's March 2023 proposal "Biotechnological Transformation (BX) Strategy", **<u>we outline key initiatives for the government's next Bioeconomy Strategy due in June 2024.</u>**



# Ⅱ. Domestic and International Trends

- International competition in biotechnology is intensifying.
- Japan must strategically allocate resources to key initiatives.

- Biotechnology is designated as a target sector for government-wide **investment expansion in the Basic Policy on Economic and Fiscal Management and Reform 2023** and as part of **economic security in the K Program**
- Various ministries are advancing initiatives in white, green, and red biotech sectors

- Issued executive order to advance domestic biotech industry (Sept 2022), set target to **replace 90% of plastics with bio-based sources within 20 years** (March 2023)

- Steadily **advancing regulation** including a policy framework for biobased, biodegradable and compostable plastics (Nov 2022) and regulation on deforestation-free products (June 2023)

- **Listed bio as a priority science and technology area**, and released National Vision for Engineering Biology (Dec 2023)

- Released 14th Five-Year Plan for Bioeconomy Development (May 2022)

- First country to **approve lab-grown meat**
- Hosted Synthetic Biology Global Forum (Feb 2023)

- Prioritizing biotech as a **biomass resource-rich country**

- Biotech industry development under Vision 2030 plan

# Ⅲ. Cross-Sectoral Key Initiatives

**Creating an issue-oriented roadmap**

**Visualizing and strengthening supply chains**

**Enhancing the pathway from basic research to application**

**Enhancing the framework for advancing biotech strategy**

## Ⅲ. Cross-Sectoral Key Initiatives

# 1. Creating an issue-oriented roadmap


- Current roadmaps framed **in terms of technology and markets** lack a clear connection to the issues the bioeconomy could potentially solve.
- **The 2030 target is relatively near-term**, and predictability of return on investment is low for large-scale capital investments like those in white biotech.


- **An issue-oriented roadmap** should be developed that uses backcasting to plot technologies and markets against the milestones necessary to solve each issue, with **a long-term target of 2040 or 2050**.
- Additionally, alongside identifying Japan's strategic advantages, it is crucial to **monitor and analyze global technological trends** and swiftly revise roadmaps as needed.

## Ⅲ. Cross-Sectoral Key Initiatives

# 2. Visualizing and strengthening supply chains

**Issues**

- As with semiconductors, securing **stable and cost-competitive raw materials** is important from an economic security perspective.

**Efforts**

- **Visualizing** the process from sourcing raw materials, transport, storage, manufacturing, and going to market to **build a resilient supply chain**.
- **Non-edible biomass** such as wood or grasses are currently the predominant sources for white and green biotech.
- For red biotechnology, it is essential to consider the risks associated with the procurement of **raw materials and component supplies related to allogeneic cells and cell cultures**.

## Ⅲ. Cross-Sectoral Key Initiatives

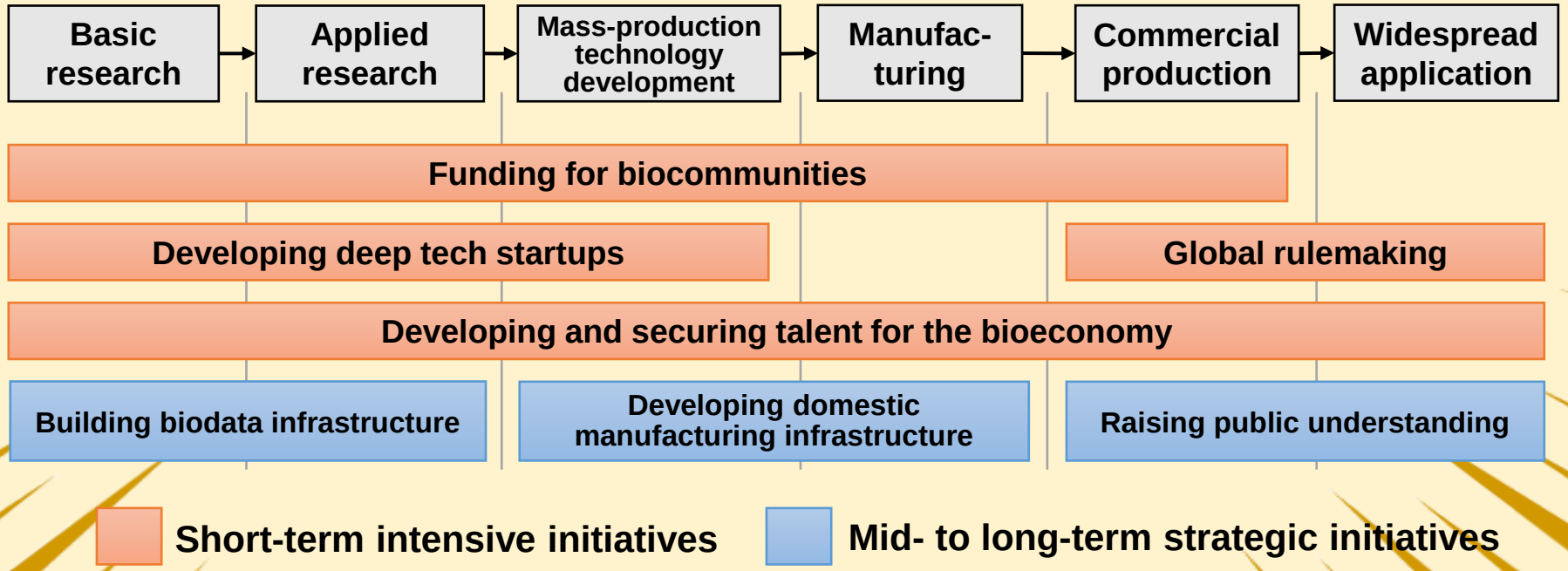
# 3. Enhancing the pathway from basic research to application

**Issues**

- Biotechnology, which is a deep tech, faces numerous challenges including funding and public understanding, in addition to the challenges of technology development.

**Efforts**

- Strengthening the pathway from basic research to real-world application and dissemination.



## Ⅲ. Cross-Sectoral Key Initiatives

# 3. Enhancing the pathway from basic research to application

### Funding to stimulate development of biocommunities

- Thorough ongoing examinations for certifying and **ensuring quality** of biocommunities
- **Funding to secure talent** needed to support community management and intellectual property

### Developing deep-tech startups

- **Strengthening support systems for intellectual property and related areas** through funding for biocommunities
- Enhancing presence for global investors by **attracting** biotech-savvy **overseas venture capitalists**, creating a continuous funding environment tailored to each phase

**Short-Term**

### Developing and securing talent for the bioeconomy

- **Encouraging workforce mobility (from large corporations to startups or academia)**: Including loaning talent to startups, side jobs, and better pay for intellectual property and legal positions in academia
- **Developing biomanufacturing talent**: Expanding government training programs, corporate internships, etc.
- **Leveraging doctoral talent**: Encouraging PhDs to contribute as both researchers and venture capitalists with tech expertise
- **Beginning at educational stage**: Integrating biotech-related lectures and practical labs throughout the university curriculum

### Global rulemaking

- To participate in global rulemaking, it is essential **to release Japan's biotech strategy in English to raise international recognition**
- **Participation in major international conferences and events**, including hosting satellite events at World Expos and similar venues
- Active participation in discussions on **DSI (Digital Sequence Information) and biosecurity**

# Ⅲ. Cross-Sectoral Key Initiatives

## 3. Enhancing the pathway from basic research to application

### Building biodata infrastructure

- Government-led **expansion of data integration and development of big data infrastructure**
- Companies are also promoting **data sharing and utilization in collaborative domains**

**Mid- to Long-Term**

### Developing domestic manufacturing infrastructure

- Government support is essential in the developing stages of the bioeconomy
- **Proactive fiscal support** to promote private facility investments for CMOs, CDMOs, and other organizations
- Support for manufacturers of consumables, component materials, analytical and measurement equipment ~~manufacturers~~
- Developing an environment where **academia and startups can use CMOs, CDMOs, etc. at low cost**

CMO: Contract Manufacturing Organization

CDMO: Contract Development & Manufacturing Organization

### Raising public understanding

- Japan has **a deep historical connection with biotechnology** through fermented foods, rice breed improvement, etc.
- Persistently engaging in **science communication** to highlight the utility of biotechnology, its contribution to economic growth, and the scientific risks involved is vital

# Ⅲ. Cross-Sectoral Key Initiatives

## 4. Enhancing the framework for advancing biotech strategy

**Issues**

- Compared to initiatives in space development and healthcare outlined in the Basic Policy on Economic and Fiscal Management and Reform 2023, the government's framework for the promotion of biotechnology is insufficient.

**Efforts**

- Increasing secretariat staff, establishing an organizational framework, and extending budgetary authority.

| | | Space | Healthcare | Biotech |
|---|---|---|---|---|
| Market size circa 2030 | | About 8 trillion yen*1 | Over 33 trillion yen*2 | About 92 trillion yen*3 |
| Governmental framework for advancement | Command | Strategic Headquarters for Space Development (Dir. Gen.: Prime Minister) | Headquarters for Healthcare Policy (Dir. Gen.: Prime Minister) | Integrated Innovation Strategy Promotion Council (Chair: Chief Cabinet Secretary) |
| | Established by | Basic Space Act | Act on Promotion of Healthcare Policy | Cabinet decision |
| | Dedicated secretariat | Yes (Cabinet Office National Space Policy Secretariat) | Yes (Cabinet Office National Healthcare Policy Secretariat) | No (within the Secretariat of Science, Technology and Innovation Policy, Cabinet Office) |
| | Related ministries and agencies | MEXT, METI, MIC, MOD, JAXA, among others | MEXT, MHLW, METI, AMED, among others | METI, MAFF, MHLW, MEXT, NEDO, among others |
| | Budget size | Around 900 billion yen*4 | Around 270 billion yen*4 | Around 1 trillion yen*4 |
| Reference | | *1: Early 2030s (Basic Space Plan) *2: 33 trillion yen as of 2025 (Healthcare Policy), partial overlap with the red biotech market *3: As of 2030 (Bioeconomy Strategy 2020) *4: Includes fund projects | | |

## Ⅳ. Key Initiatives by Sector of Application

# 1. White Biotech (manufacturing & energy)

**Developing markets receptive to bioproducts**

- Bioproducts are **higher-cost** compared to fossil fuel-based products
- Establishing international standards for quantifying the **environmental impact of bioproducts (e.g., LCA, CFP)**, and developing regulations for translating these values into **economic** terms through credits and other mechanisms
- Exploring the **need to mandate a specific percentage of bioproduct adoption**, alongside considering subsidies to bridge cost disparities

LCA: Life Cycle Assessment, CFP: Carbon Footprint

**Securing raw materials**

- Securing stable and cost-competitive raw materials is essential
- **Relevant ministries need to cooperate to develop plans that address primary production**, regarding securing and utilizing **domestic woody biomass** and other underutilized resources
- Over the medium to long term, it is essential to develop standards and certifications for securing and tracing **CO2, methane, and hydrogen**

## Ⅳ. Key Initiatives by Sector of Application

# 2. Green Biotech (food & plants)

**Building a domestic marketplace for cell-based food products**

- Cultivated meat and precision fermentation products are currently on the market in Singapore and the US
- In Japan, the market environment is underdeveloped due to **stalled discussions regarding safety and risks**

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- Establishing safety standards and guidelines for **cultivated meat tasting at the 2025 Osaka-Kansai Expo** is urgently needed
- Immediate action is also needed to prepare the market environment for **precision fermentation products**

**Supporting the development of global markets for cell-based food products**

- Support for **global expansion** of Japan's food tech companies is vital

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- Promoting rulemaking regarding the **definition and safety standards for cell-based food products** (including international standardization)

**Promoting the use of and accelerating the recycling of domestic woody biomass resources**

- Encouraging greater utilization of domestic resources is important from an economic security perspective

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- **Advancing the development, production, and adoption of wood products** (e.g., standardization of CLT panels)
- **Promoting cascading use**
- Production of domestic materials through **forestry funds** and creating carbon credits

CLT: Cross Laminated Timber
Cascading use: Using wood for material, reusing for paper or other goods, and finally as fuel

## Ⅳ. Key Initiatives by Sector of Application

# 3. Red Biotech (medical & healthcare)

**Strategic R&D framework to enhance drug discovery capabilities**

- Building a **broad base of basic research** as a foundation for red biotech

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- A clearly structured national framework is required: **public funding** for broad-ranging academic research, and **private funding** for phases leading to real-world implementation such as clinical trials
- In academic research, extensive support is crucial **to broaden the diversity of research fields** nationwide

**Appropriate assessment of a diverse variety of innovations**

- Drug discovery is a deep tech and thus high-risk, high-return

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- **New pricing models that reflect the diverse values and characteristics of innovations**, including their medical economic impact, are urgently needed to ensure that returns are proportionate to the risks involved

**Strengthening capabilities for conducting clinical trials swiftly and efficiently**

- Improving performance of global clinical trials is essential

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- Expediting measures such as the **standardization and digitalization** of clinical trial procedures and documents, along with the promotion of **international regulatory alignment in pharmaceuticals**
- Promoting **medical DX** such as standardized electronic medical records, and **strengthening clinical trial networks** centered on core clinical research hospitals

# Ⅴ. Industry Commitment

**Specific efforts by companies**

- Numerous companies have established ambitious objectives and initiated targeted actions to address societal issues and foster economic growth through biotechnology (see pp.15–16)

**Actions to implement key initiatives**

**Considerations for real-world application of innovation from academia**

- Proposals to address barriers to the growth and expansion of biotech and other startups emerging from domestic universities are scheduled for release in fiscal 2024

**Advancing a plan for global standardization in the bioeconomy**

- White: focusing on raw material standards. Green: establishing safety standards for cultivated meat. Red: aligning global regulations for regenerative medicine along with setting quality standards for related industry products

**Expanding the base of industry participants and creating networking opportunities**

- Communication and dialogue with domestic and international stakeholders
- Encouraging collaboration with biocommunities
- Holding biotech-focused KIX events
- Utilizing Keidanren Slack

**Conducting reviews**

- Periodically assessing the progress of initiatives outlined in proposals, and issuing additional proposals as necessary

KIX (Keidanren Innovation Crossing) is a networking event organized by Keidanren for major corporations and startups

# Reference: Issue-Oriented Initiatives by Various Companies (Part 1)

**Green Trans-formation**

**Circular Economy**

**Nature Positive**

**Food Security**

- **Ajinomoto:** Aiming to achieve a 50% reduction in GHG emissions (Scope 1 & 2), zero plastic waste, and 100% sustainable sourcing of key raw materials by 2030, plus a 50% reduction in food loss by 2025.
- **Kirin Holdings:** Aiming to increase the recycled resin content in PET bottles to 50% by 2027 to promote the recycling of resources in Japan, and exploring adoption of PET bottle resin derived from non-edible plant sources to reduce reliance on petroleum resources.
- **Toyobo:** Initiatives underway for developing a revolutionary production system to expand the use of mannosylerythritol lipids (MELs), a microbial-derived biosurfactant selected for NEDO's Bio-Manufacturing Project. Planning to develop new applications such as agricultural spreaders, feed additives, and sanitary material coatings by around 2025.
- **Teijin:** Selected for the NEDO Bio-Manufacturing Project for the development of bio-upcycling technology to produce useful chemicals from unused natural resources. Developing bioprocessing technology for manufacturing high-performance fiber materials.
- **Nippon Paper:** Aiming to start commercial production of bioethanol from domestic sources in fiscal 2027 (tens of thousands kL/year) and obtain certification as purely domestic materials for CORSIA-compliant fuel.
- **Nippon Paper:** Planning to register projects equivalent to 200,000 tons of forest carbon absorption credits in its company-owned forests by fiscal 2027.
- **Nippon Paper:** Aiming to achieve the goals for adoption of elite trees under the Green Food System Strategy by developing production capacity for 10 million elite tree seedlings per year by fiscal 2030, strengthening the domestic supply chain for woody resources used in green and white biotech.
- **Sumitomo Forestry:** In 2023, established the Eastwood Climate Smart Forestry Fund I in the US and began operations in July with 10 participating Japanese companies and assets of about 60 billion yen. Planning to expand operations to forests in Japan, Asia, and Oceania regions (2030 target, assets of 100 billion yen). The fund allows for significant expansion of properly managed forests, contributing to global climate change mitigation and biodiversity conservation.
- **Sumitomo Forestry:** Establishing a timber industrial complex (2030 target, domestic material usage of 1 million $m^3$/year) to improve the efficiency of domestic forestry and timber production, and increase carbon sequestration by substituting with wood-derived materials. Increasing the amount of harvested wood products (HWP) processed and produced to boost carbon sequestration.
- **Sumitomo Forestry:** Advancing decarbonization across the industry by promoting Zero Energy Houses (ZEH), Zero Energy Buildings (ZEB), Low Carbon Construction Material (LCCM) housing, and net-zero carbon buildings, and by establishing decarbonization design standards like One Click LCA × EPD.
- **Ajinomoto:** Promoting the development of next-generation food systems with low environmental impact such as plant-based foods, cultivated meat, and precision fermentation.
- **Nippon Paper:** Expanding the cellulose livestock feed business derived from domestically sourced wood, aiming to replace imported forage with locally produced feed. Pilot projects are underway at more than 40 user sites as of April 2023.

# Reference: Issue-Oriented Initiatives by Various Companies (Part 2)

## Well-being

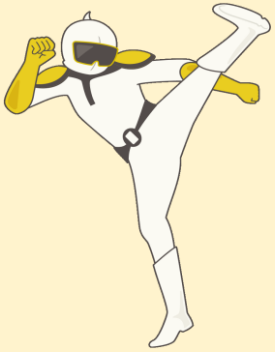
- **Kirin Holdings:** Combining insight of Kirin Group companies and Otsuka Pharmaceutical Factory to launch a project using biotechnology to solve quality issues of raw materials in existing compounds widely circulating on the market. Aiming for global sales of over 100 billion yen and starting construction of facilities for clinical trial drug substances with a product launch target of 2029.
- **Sumitomo Pharma:** Aiming to expand Japanese-originated iPS cell technology overseas and will start corporate clinical trials of iPS cell-derived products in the US in 2024.
- **Sumitomo Pharma:** Aiming to launch the world's first iPS cell-derived product in fiscal 2024.
- **Sumitomo Pharma:** Aiming for global sales of over 100 billion yen in the regenerative and cellular medicine business by fiscal 2032.
- **Ajinomoto:** Acquired US-based Forge Biologics for roughly 82.8 billion yen in 2023 to grow its gene therapy business.
- **Takeda Pharmaceutical:** Developing an R&D system and advancing business strategies through a global drug discovery ecosystem to swiftly deliver innovations to patients worldwide.
- **AGC:** Plans to build one of the largest domestic CDMO facilities in Yokohama within Greater Tokyo Biocommunity (GTB), which can switch to vaccine production during a pandemic, and will be operational in 2026.
- **Daiichi Sankyo:** Obtained domestic approval in August 2023 for additional immunization using a monovalent mRNA vaccine targeting the original COVID-19 strain supported by AMED and MHLW's vaccine initiative.
- **Daiichi Sankyo:** Obtained partial change approval for COVID-19 vaccine for the Omicron strain XBB.1.5 in November 2023, supplying 1.4 million doses as the first domestically produced mRNA vaccine.
- **Daiichi Sankyo:** Signed a global agreement with Merck (Rahway, NJ) for development and commercialization of DXd-ADC 3 products, aiming for rapid and widespread delivery to cancer patients worldwide.
- **Teijin & Mitsui Fudosan:** Constructing the Kashiwanoha Regenerative Medicine Platform, which utilizes the CDO facility adjacent to the National Cancer Center Hospital East to accelerate the development of regenerative medicine products.
- **Teijin:** Enhancing the global reach of Japanese-developed innovations and speeding up the development of foreign innovations in Japan by establishing a shared manufacturing platform with international CDMOs.
- **Teijin:** Leveraging the business experience of its group company Japan Tissue Engineering to construct an autologous cell business platform at three domestic locations (Gamagori in Aichi Prefecture, Kashiwa in Chiba Prefecture, Iwakuni in Yamaguchi Prefecture)
- **Chugai Pharmaceutical:** Planning to double R&D output over 10 years and deliver innovative in-house developed global products to the market every year. Their 2024 plan includes an investment of 171 billion yen to bolster drug discovery technology infrastructure and related areas.
- **Chugai Pharmaceutical:** Investing 76.7 billion yen from 2023 to 2027 in new construction and modification of domestic manufacturing facilities for bio drug substances and other products to double R&D output.
- **Astellas Pharma:** Aiming for sales of over 500 billion yen by fiscal 2030 from innovative products in gene and cell therapy.

# Ⅵ. Conclusion

This proposal outlines key measures aimed at achieving Biotechnology Transformation (BX).

BX is a key to facilitating industrial restructuring using biotechnology and fulfilling Keidanren’s vision of sustainable capitalism.

Keidanren is committed to achieving BX in collaboration with stakeholders including the government, academia, and startups.



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