



Bio CDMO & Life Sciences Business Briefing

December 14, 2023

FUJIFILM Holdings Corporation

**NEVER
STOP**

Forward-looking statements, such as those relating to earnings forecasts and other projections contained in this material, are management's current assumptions and beliefs based on currently available information. Such forward-looking statements are subject to a number of risks, uncertainties, and other factors. Accordingly, actual results may differ materially from those projected due to various factors

FUJIFILM
Value from Innovation

Speakers

FUJIFILM Corporation, Corporate Vice President
General Manager, Life Sciences Strategy Headquarters
General Manager, Bio CDMO Div.
Chairman, FUJIFILM Diosynth Biotechnologies

Toshihisa IIDA

FUJIFILM Corporation, Corporate Vice President
Deputy General Manager, Life Sciences Strategy Headquarters
General Manager, Life Sciences Business Div.
Chairman & CEO, FUJIFILM Irvine Scientific, Inc

Yutaka YAMAGUCHI

FUJIFILM Corporation, Corporate Vice President
Deputy General Manager, Life Sciences Strategy Headquarters
General Manager, Bio Science & Engineering Laboratories

Takeshi YAMAMOTO

Agenda

1 Overview

2 Bio CDMO Business

3 Life Sciences Business

4 Technological Advantages

5 Environmental Strategy

6 Summary

Overview

1**Overview****2****Bio CDMO Business****3****Life Sciences Business****4****Technological Advantages****5****Environmental Strategy****6****Summary**

Toshihisa Iida

- Apr. 1991

○ Joined Fuji Photo Film Co., Ltd.
- Nov. 2016

○ General Manager, Optical Device & Electronic Imaging Products Div.
- Jun. 2020

○ Managing Director, FUJIFILM Europe GmbH(Germany)
Managing Director, FUJIFILM Europe B.V.(Netherlands)
- Jun. 2022

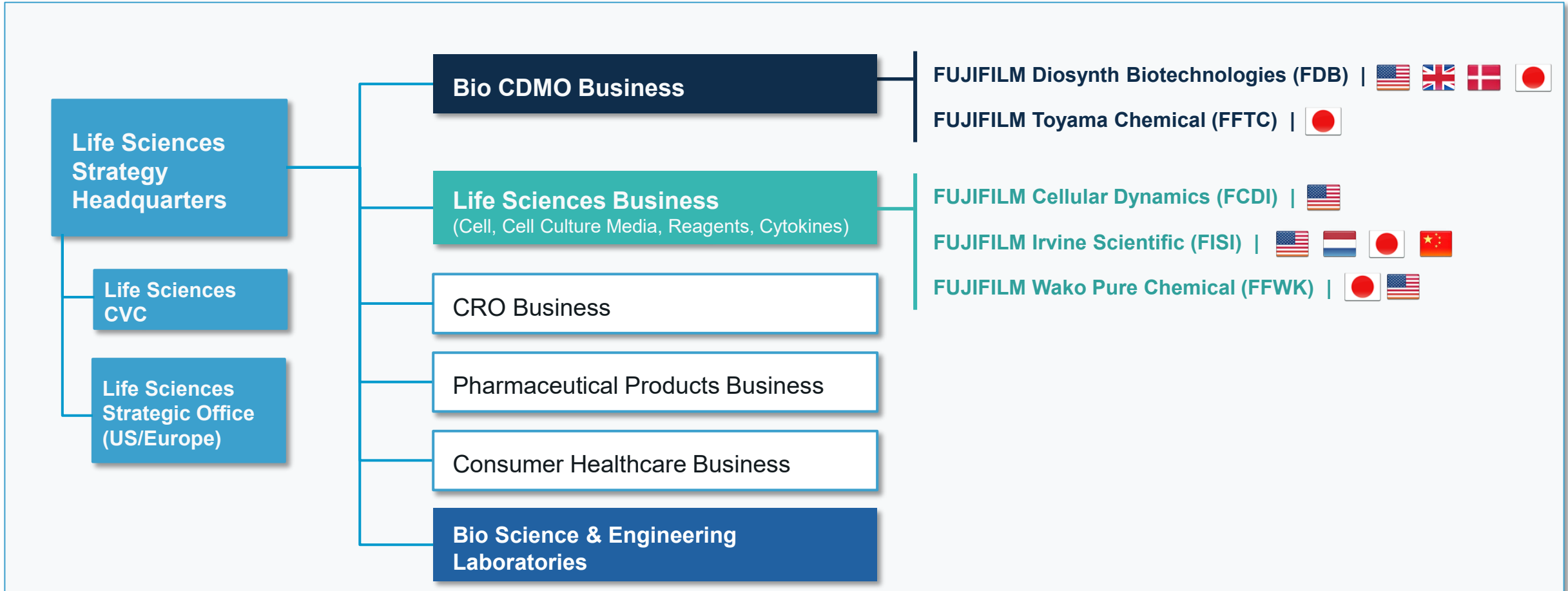
○ Corporate Vice President, FUJIFILM Corporation
Managing Director, FUJIFILM Europe GmbH(Germany)
Managing Director, FUJIFILM Europe B.V.(Netherlands)
(in charge of Photo Imaging Products Div., Europe, the Middle East, and Africa)
- Apr. 2023

○ Corporate Vice President, FUJIFILM Corporation
Senior Deputy General Manager, Bio CDMO Div.
Chairman, FUJIFILM Diosynth Biotechnologies
- Jun. 2023

○ **Corporate Vice President, FUJIFILM Corporation (Based in North Carolina, U.S)**
General Manager, Life Sciences Strategy Headquarters
General Manager, Bio CDMO Div.
Chairman, FUJIFILM Diosynth Biotechnologies

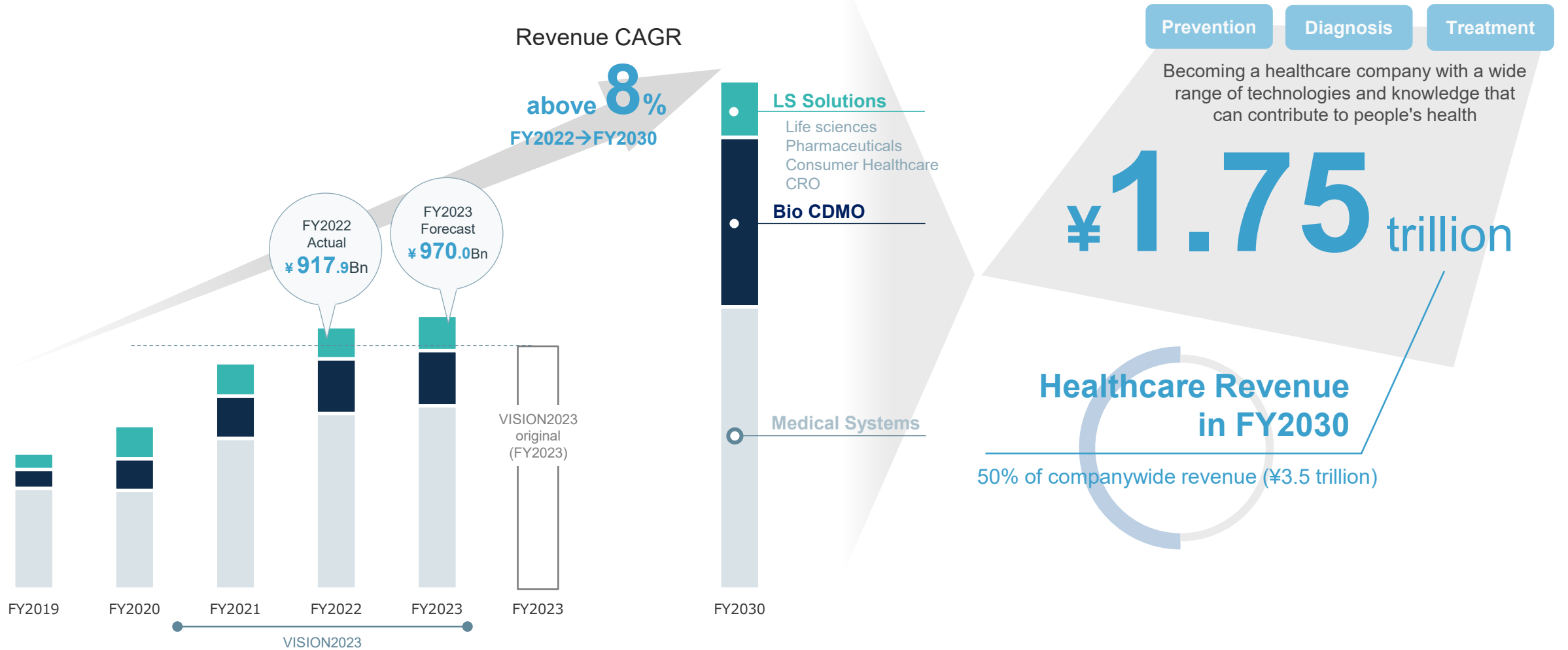
1-1 | Business Organization

Be a "The Trusted Partner" in the life science industry by delivering "End-to-end service", as a company "supporting" development and supply of cutting-edge therapeutics



1-2 | Healthcare Segment

The Healthcare segment is expected to contribute 50% of FUJIFILM Group's revenue target of ¥3.5 trillion for FY2030. Life Sciences-related business will be a key driver of growth.

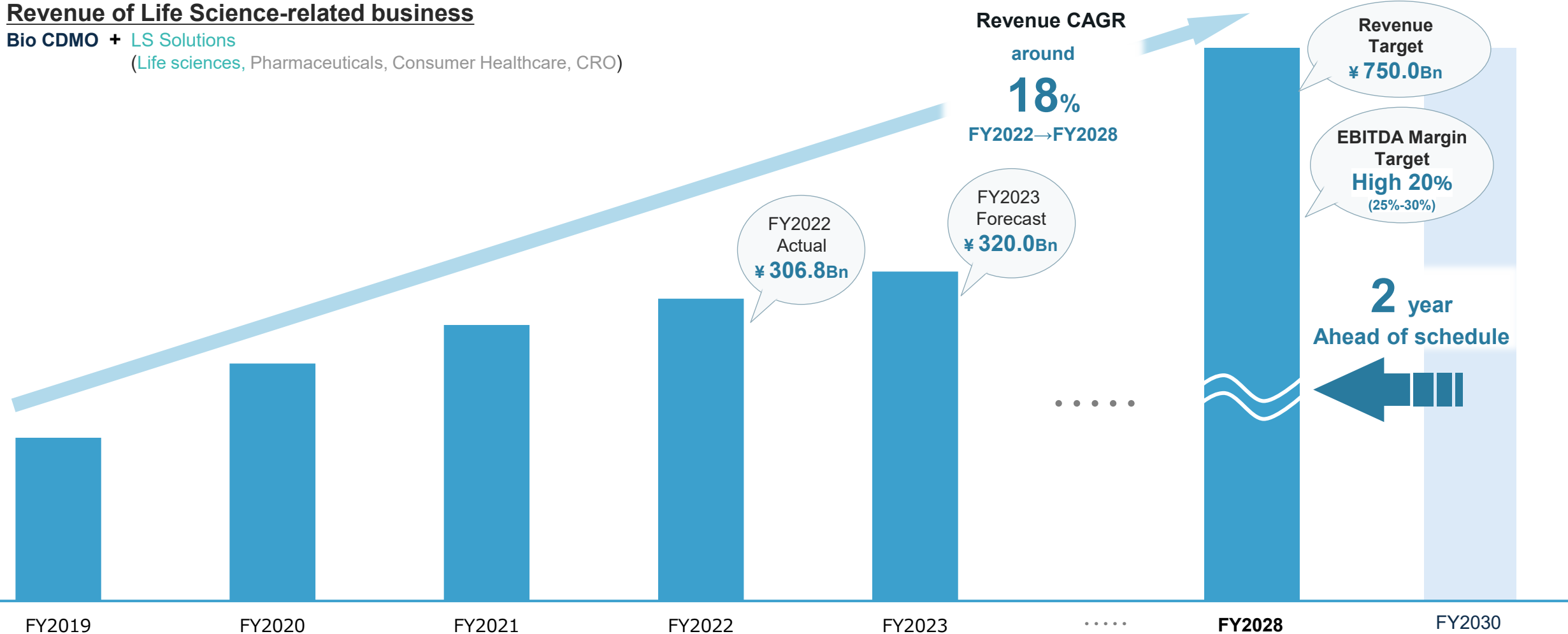


1-3 | Mid- to Long-term Target of Life science-related business

Due to the growth of Bio CDMO business, we project to achieve the targeted revenue of ¥750 billion two years ahead of schedule. We also aim to reach an EBITDA Margin in the High 20% range by FY2028.

Revenue of Life Science-related business

Bio CDMO + LS Solutions
(Life sciences, Pharmaceuticals, Consumer Healthcare, CRO)



1-4 | Market Environment

Although changes in the market environment through COVID-19 have a short-term impact in FY2022-2023, we will continue to invest based on long-term market growth forecasts to build a stable business structure

■ Bio CDMO ■ Life Sciences

Market Environment

Impact on company

Our measures / responses

- Steady demand for conventional antibody drugs
- Progress in the development of next-generation antibody drugs (ADC etc.)



- Strong performance of antibody drugs manufacturing mainly at the Denmark site



- Smooth launch of a new large-scale facilities
- Boosting capabilities to next-gen antibody drugs (ADC, etc)
- Conversion of gene therapeutic tanks for antibody drugs manufacturing (Under consideration)

- Sharp downturn in funding of biotech
- Stagnant pipeline development and decline in the number of new clinical trials



- Stagnant development orders for gene therapeutics
- Sluggish demand for cells / reagents for drug discovery support



- | Temporarily slowing down investment in gene therapeutics
- | ■ Continuing to invest in cell therapies in anticipation for long-term market growth

- Piling up components and consumables, which were mass purchased amidst SCM confusion during the COVID-19



- | ■ Write-down for inventories which nearing the end of shelf life
- Decline in culture medium as a result of clients' inventory adjustment



- | ■ Reinforcement of supply chain management

- Reassessing of suppliers and changes in SCM based on COVID experiences
- Growing significance of BCP



- | ■ Increased contracts orders as 2nd / 3rd site
- Acquiring new customers due to an increase in purchase from multiple suppliers.



- | ■ Strengthen partnerships through manufacturing near customers by leveraging our geopolitical advantage of having a global footprint

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Business Strategy for Antibody Drug

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Business Strategy for Cell & Gene Therapy

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Supply Chain Management

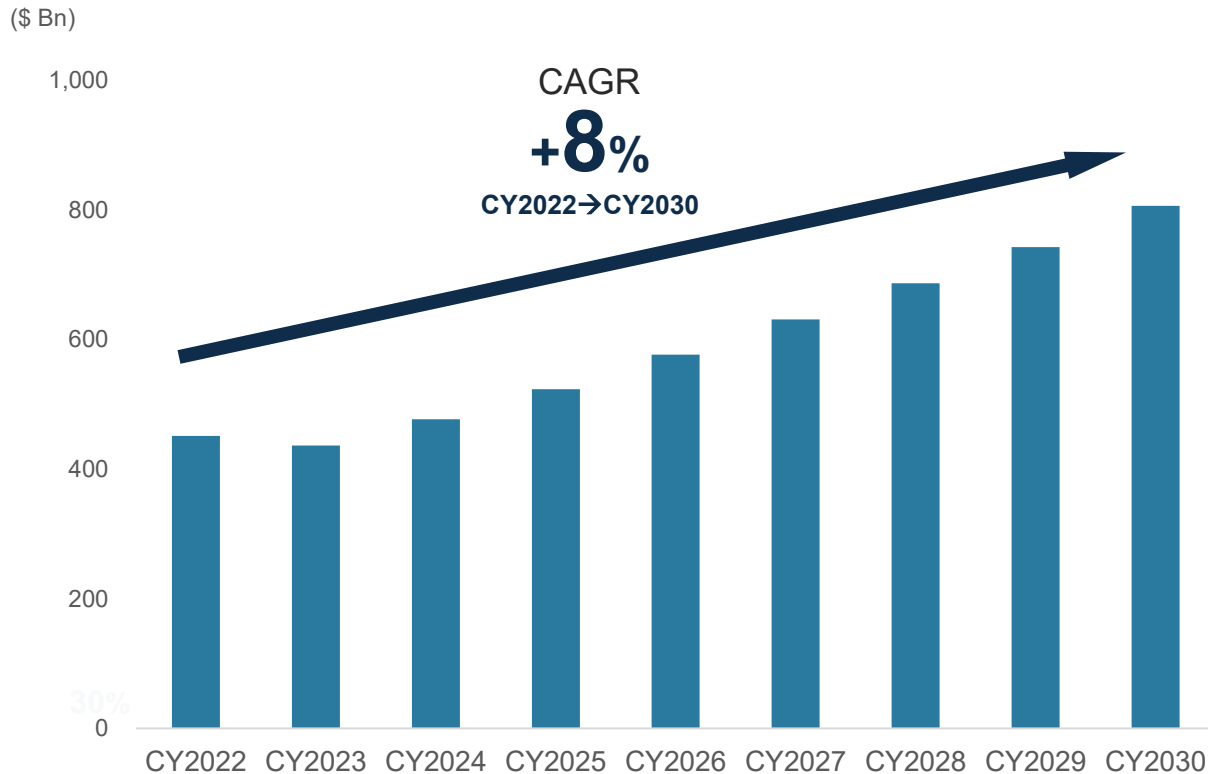
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Wrap-up

2-1-1 | Biopharmaceutical Market Trend

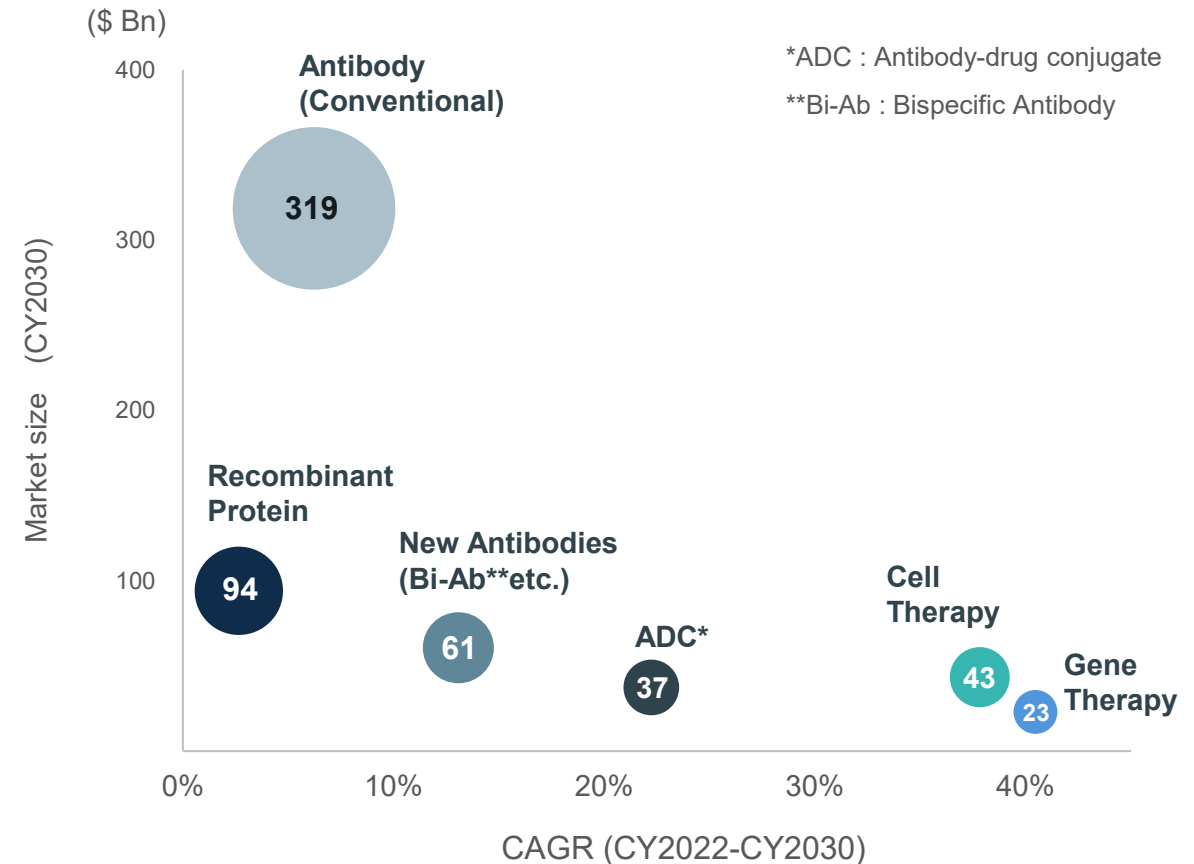
Biopharmaceutical market expands at CAGR 8%(2022→2030).
In addition to the stable growth in conventional antibody drug, the largest market, high growth is expected for new modalities such as cell & gene therapy, ADC* and Bi-Ab in the mid-long term.**

Biopharmaceutical Market



Source: Fujifilm's conjecture based on EvaluatePharma® Nov, 2023

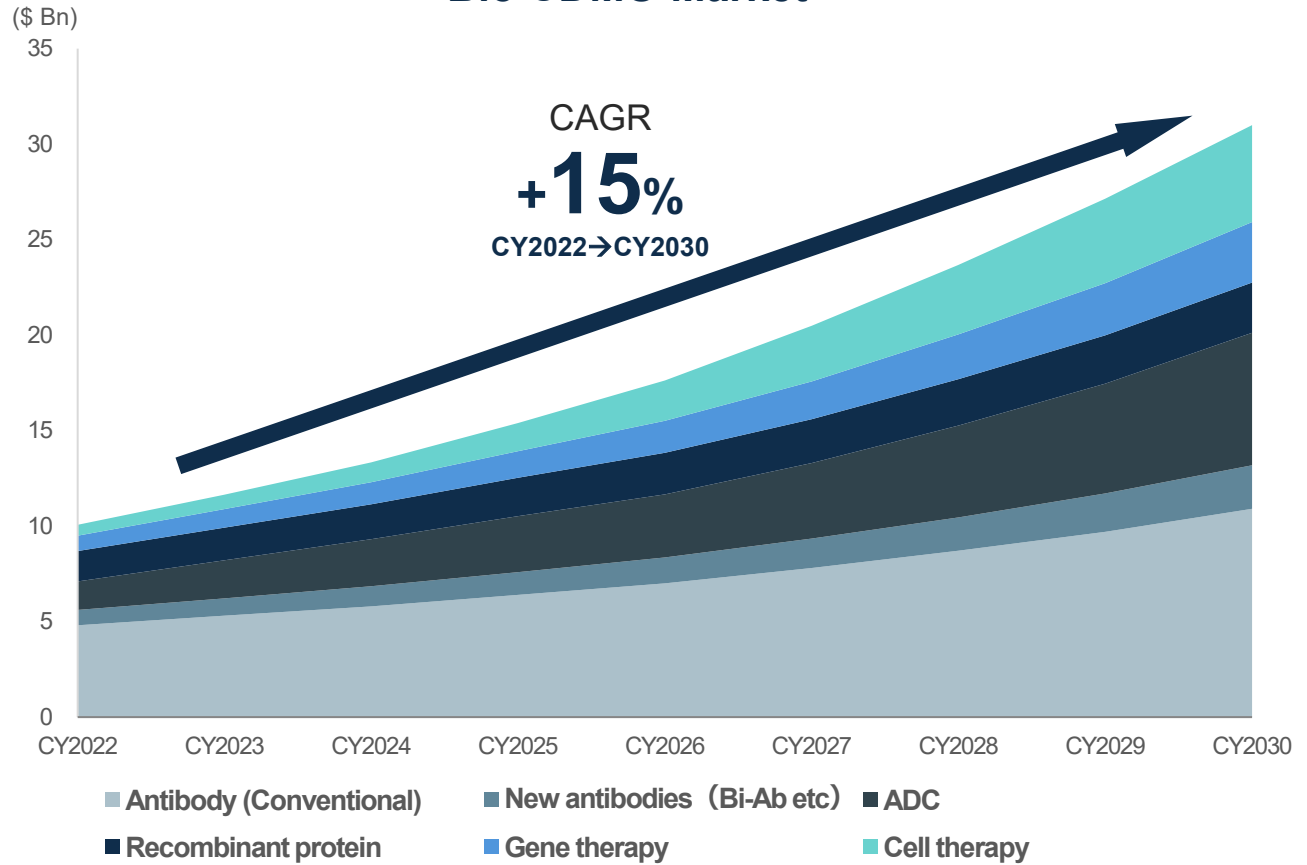
Biopharmaceutical Market Growth Rate Forecast by Major Modalities



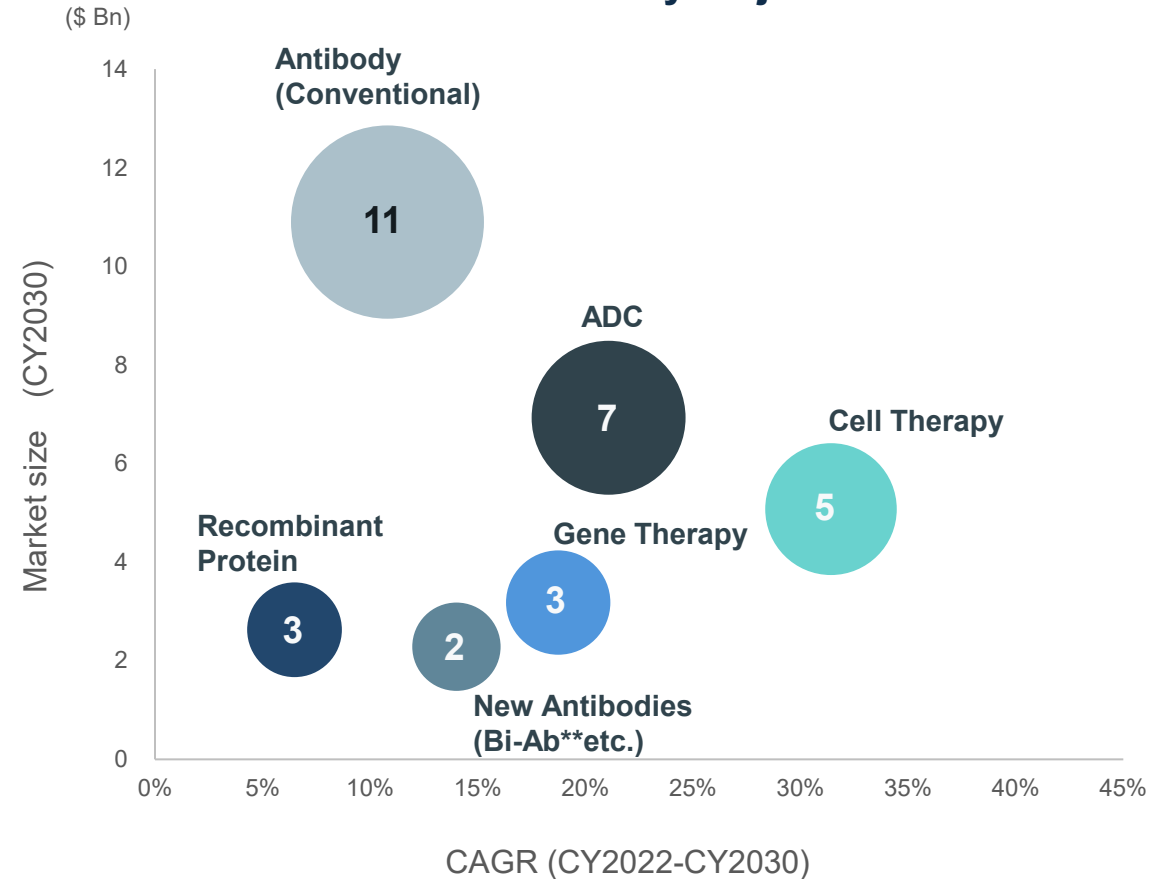
2-1-2 | Bio CDMO Market Trend

Bio CDMO market expands at CAGR 15%(2022→2030), outperforming Biopharmaceutical market. In addition to the stable growth in conventional antibody drug, new modalities (cell & gene therapy, ADC, Bi-Ab) with a high ratio of outsourcing to CDMO will grow significantly.

Bio CDMO Market



Bio CDMO Market Growth Rate Forecast by Major Modalities



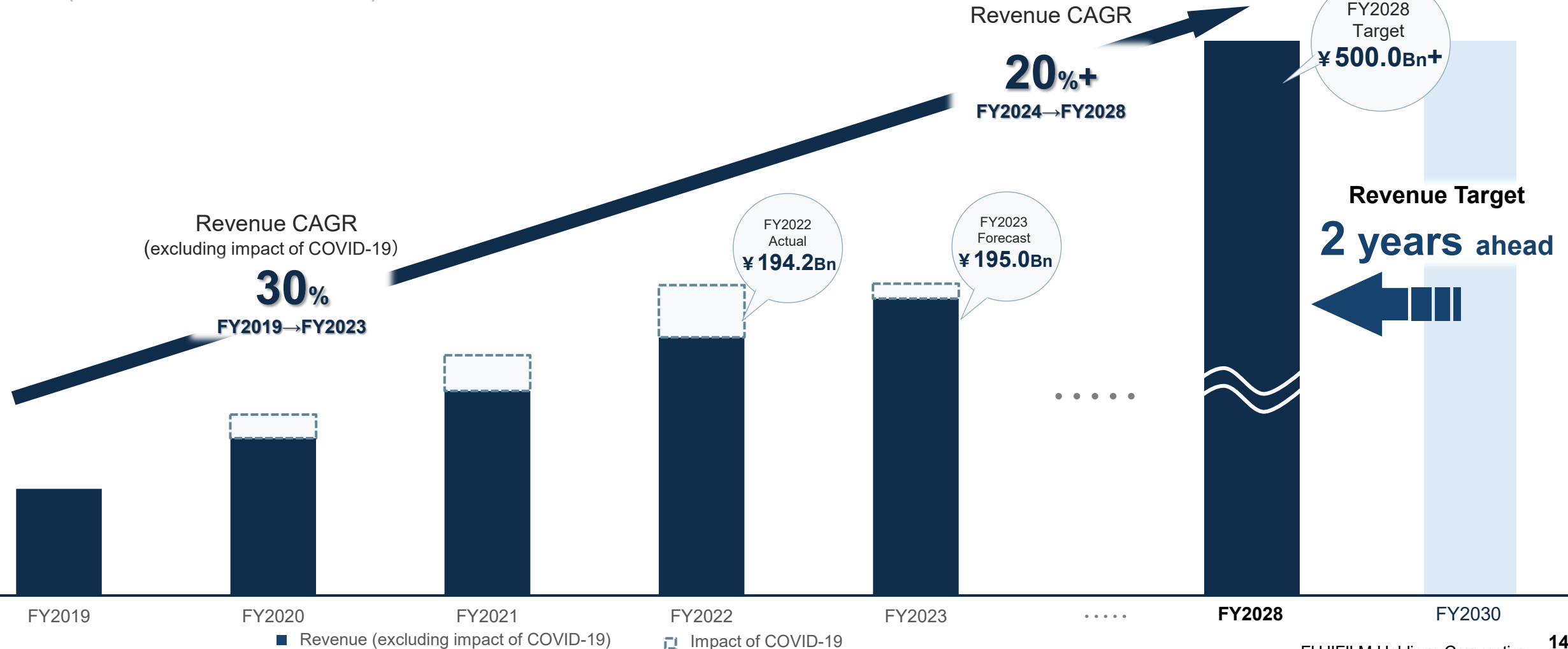
Source: Fujifilm's conjecture

2-1-3 | Business Growth Outperforming Market Expansion

Fujifilm's Bio CDMO business has achieved CAGR 30% growth after acquisition of manufacturing site from Biogen, far outperforming the rate of market average growth*.

It will grow at CAGR 20%+ in the next 5 years and achieve the revenue target of 500 billion yen in FY2028, 2 years ahead of the original schedule.

* 13% (FY2019~FY2023, in-house research)



2-1-4 | Overall Strategy for Bio CDMO Business: Redefine CDMO by "The Trusted Partner"

Supporting clients' manufacturing and process development of pharmaceuticals as their trusted partner
Pursue to be "Partners for Life"



Pharmaceutical Companies
Biotech Startups

Innovative Drug
Development

Manufacturing and Process Development
of Pharmaceuticals

Delivery of
Therapeutics



Patients

FUJIFILM

Partners for *Life*
Advancing tomorrow's medicines

kojoXTM
Supply agility through modular approaches

Expectations for CDMO

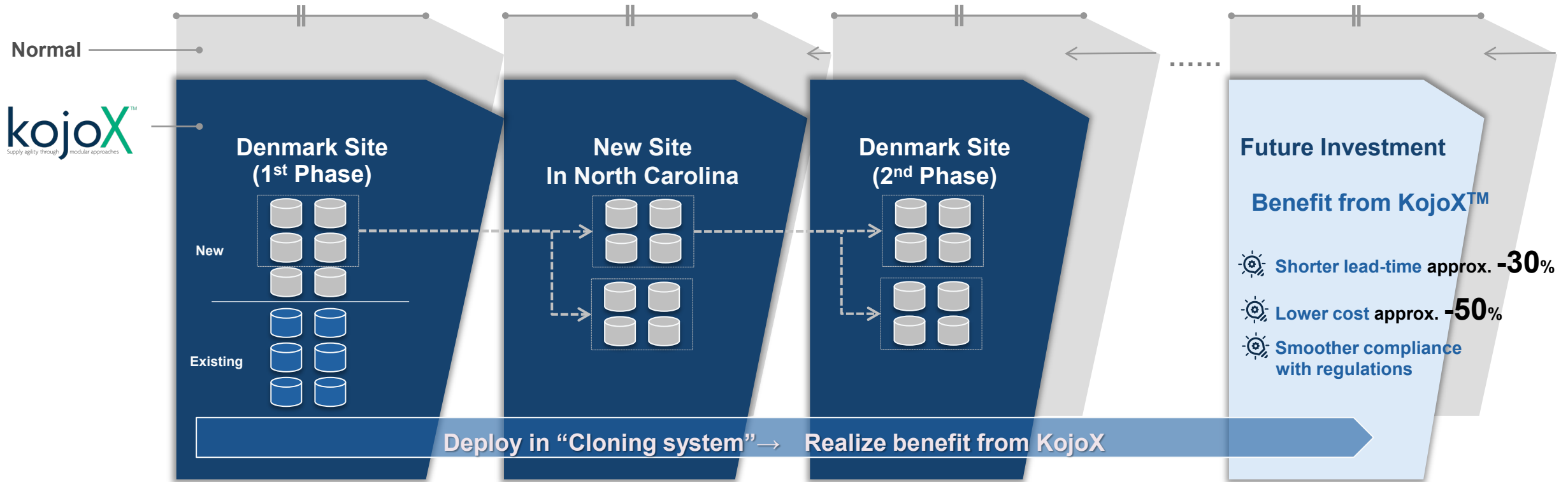
- Ample supply capacity
- Highly efficient and stable production
- Experiences in dealing with various regulations (track record)
- End-to-End service for diverse pipelines
- Rapid technology transfer to deliver new products to market
- Agility in response to clinical development stages and demand fluctuations

Fujifilm's strengths as "The Trusted Partner"

- Active investments to expand capacity
- High batch success rate (over 98%) at the large-scale manufacturing facility
- Extensive experiences and knowledge of regulatory in various countries
- Manufacturing capability catering to diverse modalities
- KojoX : Scalability (from small-medium to large) and rapid tech transfer
- Mirrored production structure in EU and USA close to customers

2-1-5 | KojoX™ : Deploy Common Design and Equipment to New Sites

By leveraging track record of existing sites, deploying common design and equipment to new sites in a cloning system (KojoX™). This contributes to a shorter lead-time, lower cost and smoother compliance with various regulations.



2-1-6 | Reinforcing End-to-End Service to Address Customer Needs

*Based on publicly available information
as of December 2023

Reinforcing support from large-scale manufacturing to fill & finish and packaging for antibody drug

Modality	Site	Major Investment*
Antibody Drug (Large-Scale Manufacturing)	Denmark	<ul style="list-style-type: none"> Expanding 20,000L x 6 bioreactors and fill & finish and packaging system Expanding 20,000L x 8 bioreactors to increase the total number of reactors in this capacity to 20
	Holly Springs NC, US	
		<ul style="list-style-type: none"> Establishing a new site with 20,000L x 8 bioreactors as well as fill & finish and packaging system

Support for a wide range of modalities and stages from early clinical phase to commercial:

Reinforcing capacity for small-medium scale manufacturing

Modality	Site	Major Investment
Antibody Drug (Small-Medium Scale Manufacturing)	Billingham, UK	<ul style="list-style-type: none"> Expanding 2,000L single-use bioreactors Developing continuous biomanufacturing system
	College Station TX, US	
Recombinant Protein	Billingham, UK	<ul style="list-style-type: none"> Conversion of gene therapeutic tanks for antibody drug (Under consideration)
Gene Therapy	Billingham, UK	<ul style="list-style-type: none"> Expanding bioreactors for microbial culture Reinforcing downstream capability
Cell Therapy	Madison, Wisconsin, US	<ul style="list-style-type: none"> Establishing a new building for process development and API manufacturing for gene therapy Expanding facilities for process development / GMP manufacturing and clean room for iPSC-derived cell therapy New Expanding facilities for process development / GMP manufacturing and clean room for a wide variety of cell therapies including donor-derived cell therapy New
	Thousand Oaks CA, US	

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2-2 | Antibody Drug

**Strong performance in manufacturing of antibody drug, mainly at the Denmark site.
To prepare for further market expansion, we will smoothly launch new large-scale facilities
and make early contribution to earnings**

■ Bio CDMO ■ Life Sciences

Market Environment

Impact on company

Our measures / responses

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- | ■ Continuing to invest in cell therapies in anticipation for long-term market growth

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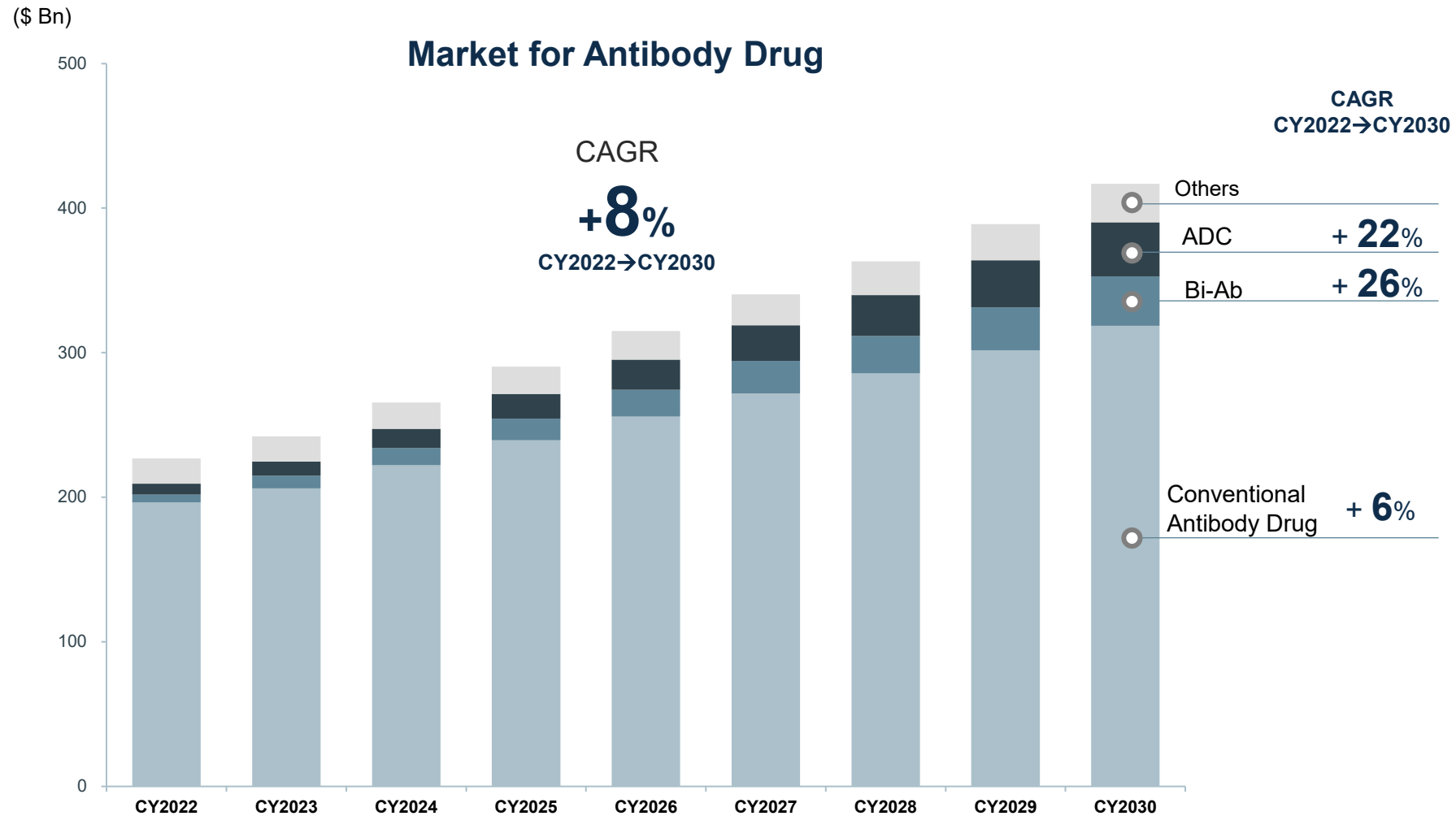
- | ■ Increased contracts orders as 2nd / 3rd site
- Acquiring new customers due to an increase in purchase from multiple suppliers.



- | ■ Strengthen partnerships through manufacturing near customers by leveraging our geopolitical advantage of having a global footprint

2-2-1 | Market Forecast for Antibody Drug

Market for antibody drug expands steadily driven by development progress of the next generation antibody drug such as ADC.



Source: Fujifilm's conjecture based on EvaluatePharma® Nov, 2023

2-2-2 | Business Strategy for Antibody Drug

Outsourcing to CDMO is increasing as pharmaceutical companies focus on R&D to develop a wide range of pipelines. Diverse capabilities (modalities / clinical development stages), manufacturing capacity, agility, track record are essential for CDMO, and Fujifilm continues to provide values to customers by leveraging our strength as “The trusted partner”.

【To be The Trusted Partner】

Fujifilm’s strength **kojoX**

Values offered to customers

Ability to offer End-to-End service * for customers’ diverse pipelines (* Process development to Commercial manufacturing)



Reducing burdens to deal with many CDMO

Manufacturing facilities from small, medium to large-scale



Providing scalability in response to clinical development stages and fluctuations in demand

State-of-the-art facilities mirroring sites in Europe and the US

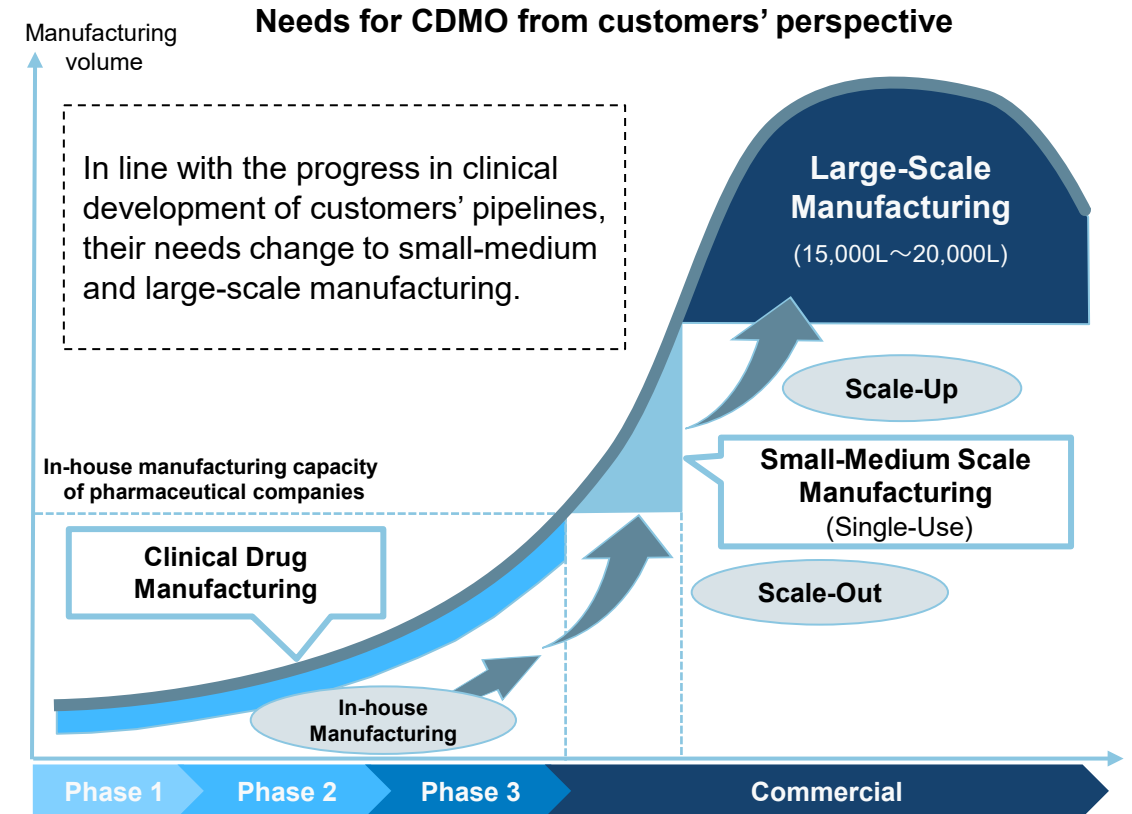


Swift transfer of products / technologies, smooth certification process

Reinforcing capacity such as 20,000L bioreactor expansion in the sites close to customers



Sense of security about stable supply in the long-term



2-2-3 | Increasing Sales and Profitability in line with Expansion of Manufacturing Capacity

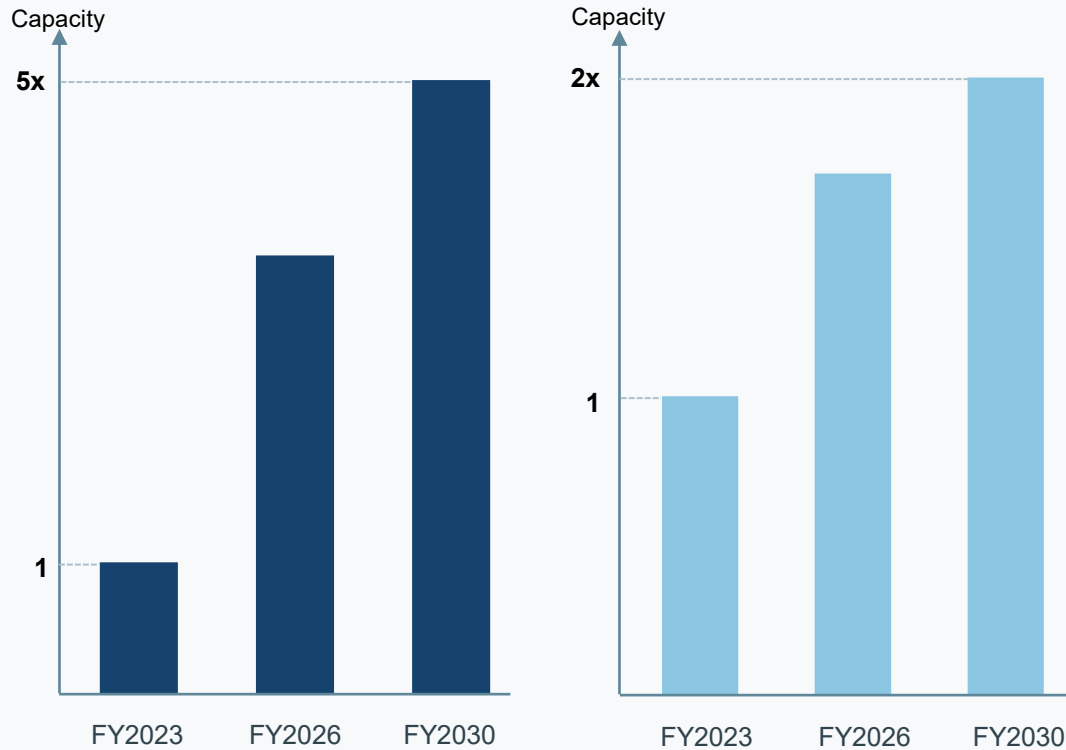
Reinforcing End-to-End service from early clinical phase to commercial manufacturing with small, medium and large-scale facilities.
 Fujifilm aims to achieve EBITDA margin 40% in FY2030
 by absorbing fixed costs through revenue growth and increasing the ratio of commercial manufacturing.

Capacity

* Vertical axis shows the percentage increase in capacity when the capacity in FY2023 is set to 1

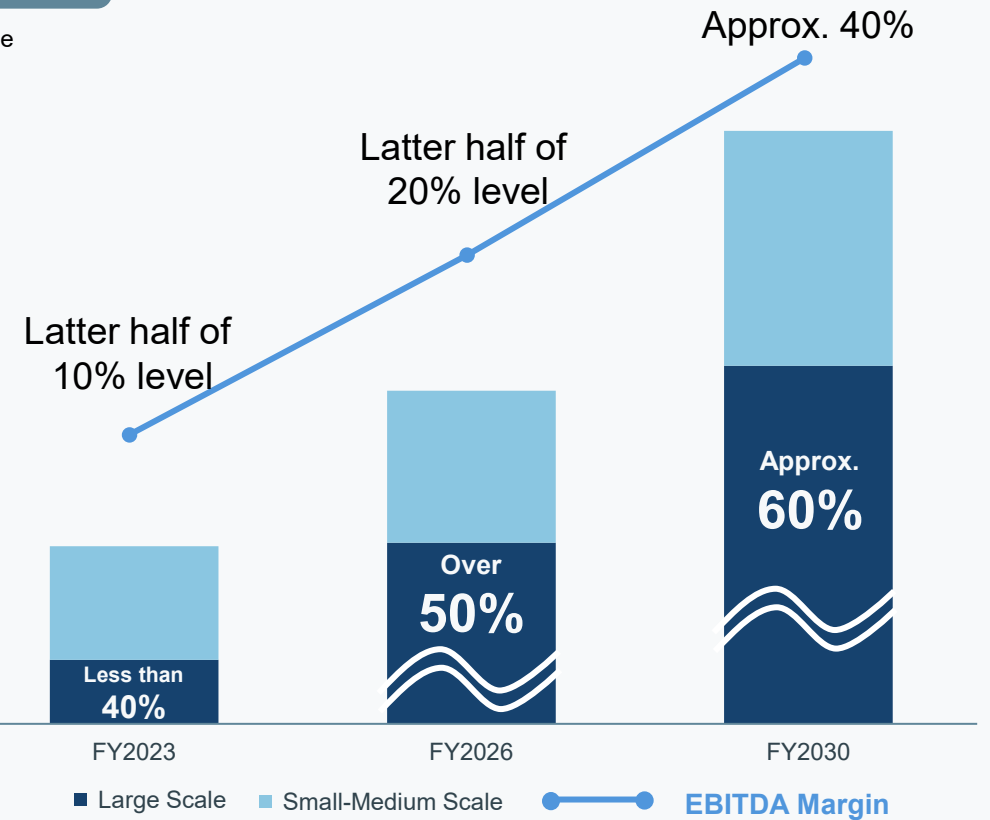
[Large Scale]

[Small-Medium Scale]



Revenue · EBITDA

Revenue

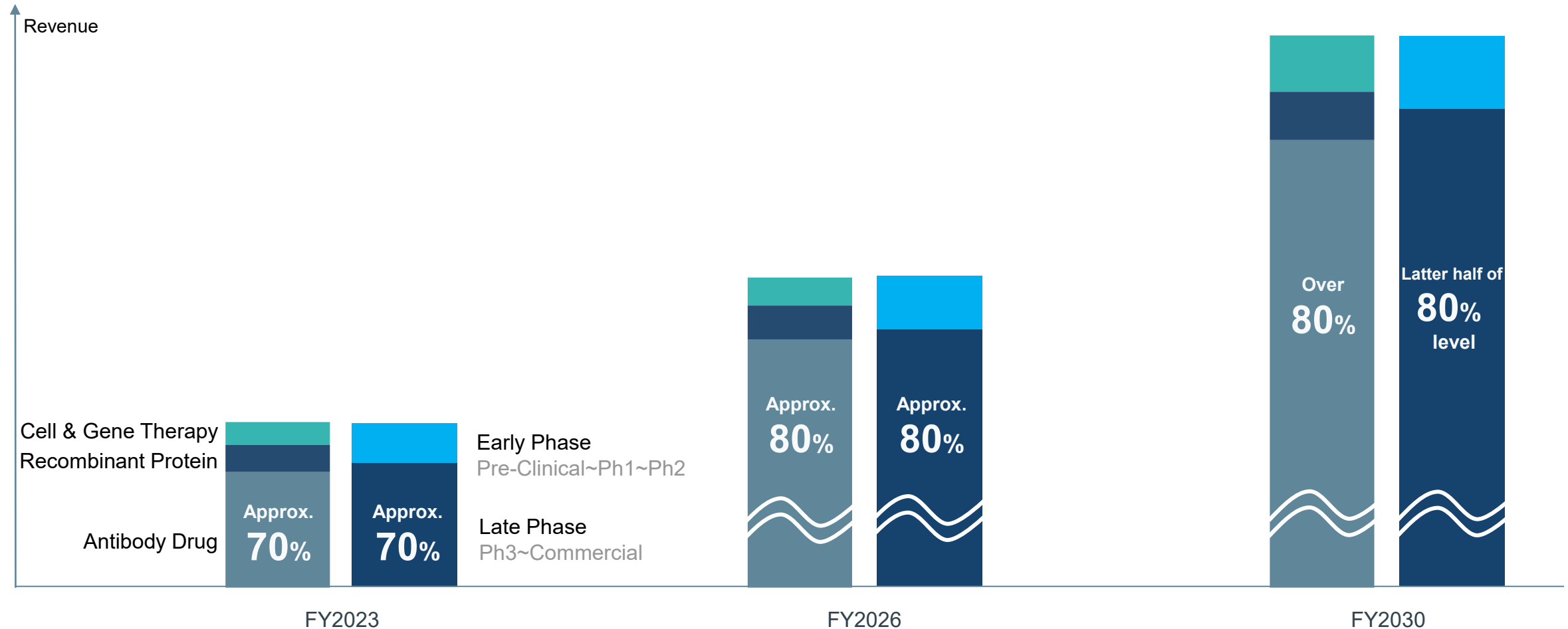


Large Scale=20,000L、 Small-Medium Scale*≤5,000L

*Small-Medium scale facilities include facilities other than those for antibody drugs (e.g. recombinant protein, gene therapy and vaccine).

2-2-4 | Breakdown for Revenue by Modalities and Clinical Development Stages

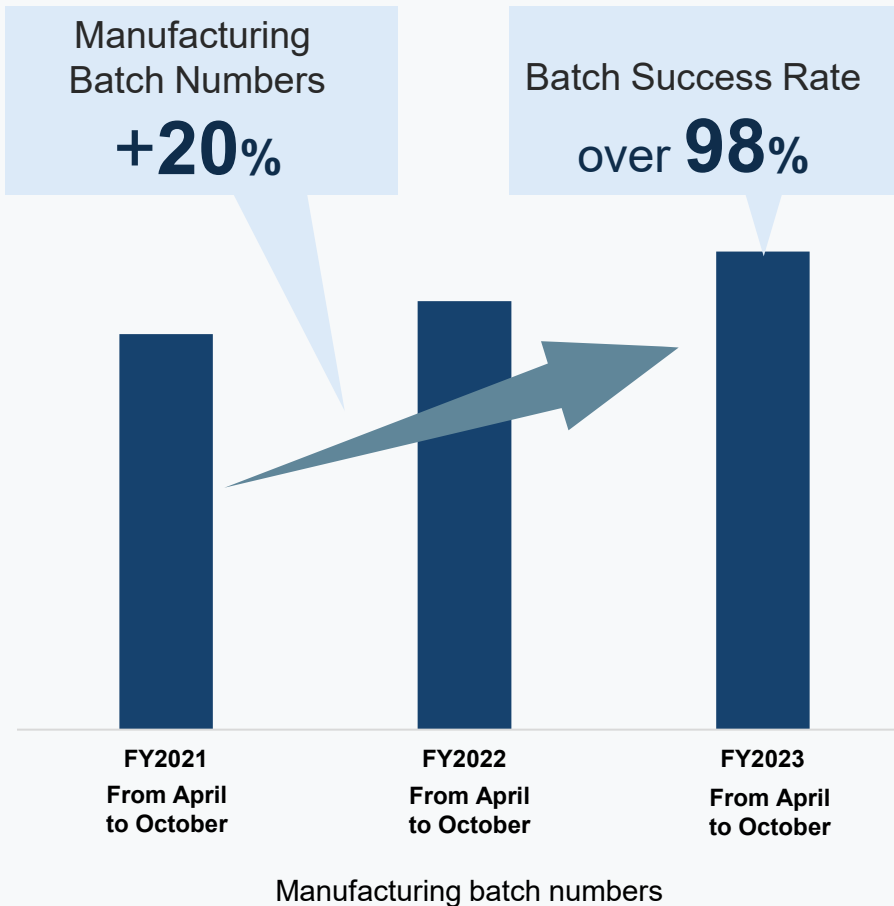
Increasing the ratio of late phase pipelines with large scale facilities contributes stable operations and earnings. These stable earnings enable us to invest in advanced therapeutics to expand future pipelines.



2-2-5 | Performance at Denmark Site

High efficiency and stable manufacturing at Denmark site has led to a steady accumulation of a track record.

High Efficient and Stable Manufacturing



Extensive Experience of Inspections by Regulatory Authorities



Inspections by regulatory authorities in various countries
35 times in total (since 2011)

Gained **Positive** result in **all** cases



Accumulated track record leads to the trusted relationships with regulatory authorities. **25%** of PAI* by FDA is approved with **on-site inspection waved**.

*Pre-Approval Inspection

Ample Capacity

Large-Scale Bioreactors for Ph3~commercial manufacturing (20,000L)

FY2022

6 units in operation



FY2026

expanding to **20** units

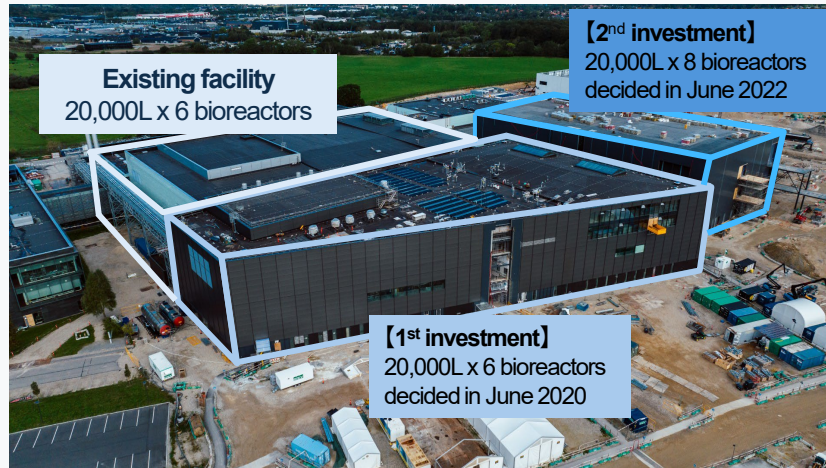
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2-2-6 | New Large-Scale Facilities: Progress toward Operation

Construction in Denmark site is 95% completed and its validation is on track.
In North Carolina, US site, overall construction is in progress without delay.
 (Weather tight ceremony was held in early November at the completion of the exterior wall construction)

Denmark Site

Expanding 20,000L x **14** bioreactors
 (1st investment **6 units** • 2nd investment **8 units**)



FY2024

FY2025

FY2026

1st Phase



2nd Phase



North Carolina, US Site

Establishing a new site with 20,000L x **8** bioreactors
 and fill finish & packaging system

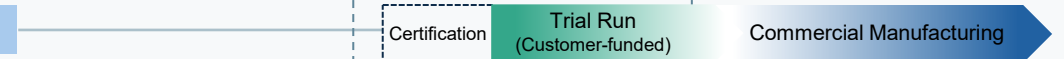


FY2024

FY2025

FY2026

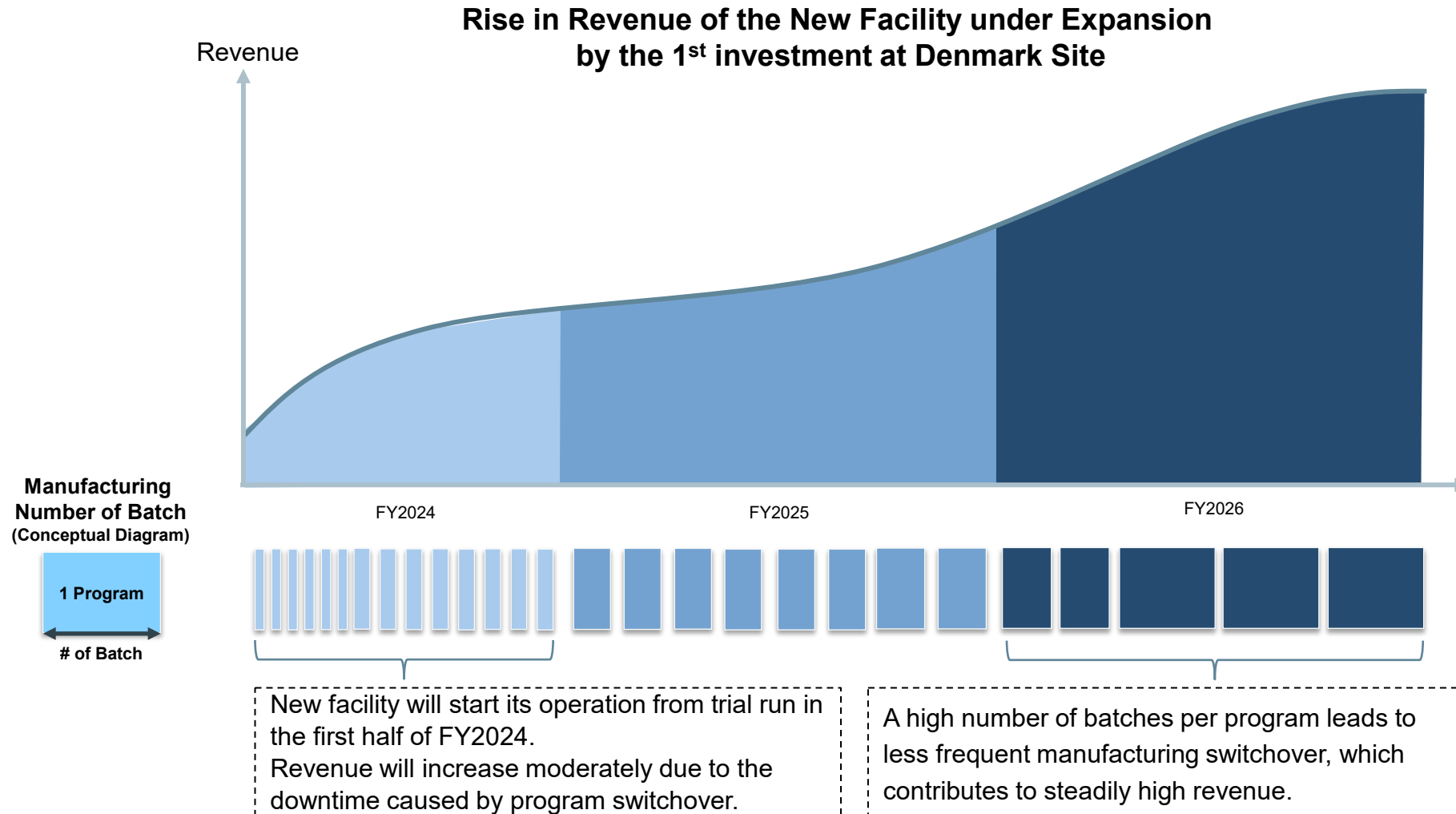
New Site



2-2-7 | New Large-Scale Facilities: Rise in Revenue after the Start of Operation

New facility at Denmark site will start its operation from trial run in the first half of FY2024, and all 6 units will begin operation in FY2024.

We will accumulate manufacturing track record steadily toward its full contribution to business growth.



2-2-8 | New Large-Scale Facilities: Commercial Activity

Almost all capacity for the new facility at Denmark site (6 Unit) is filled with signed programs for FY2025 and the first half of FY2026
In New NC Site US, Janssen Supply Group, LLC, a Johnson & Johnson company, has committed to a large-scale manufacturing suite*.

: Large bioreactors (20,000L)

Status as of each fiscal year-end

: Contract signed

: Informal agreement

: Negotiations in progress

: Facilities authority application / Trial run in progress

Progress of commercial negotiations over the last year
Updates from Dec. 2022

Progress of business negotiations over the last quarter
Updates from Nov. 2023

Denmark
Second-phase investment (8 units)

US New North Carolina site (8 units)

Denmark
First-phase investment (6 units)

Denmark in operation (6 units)

*Scheduled to conclude formal agreement by the end of this fiscal year

Building 2

Building 1

Janssen Supply Group has committed to a large-scale manufacturing

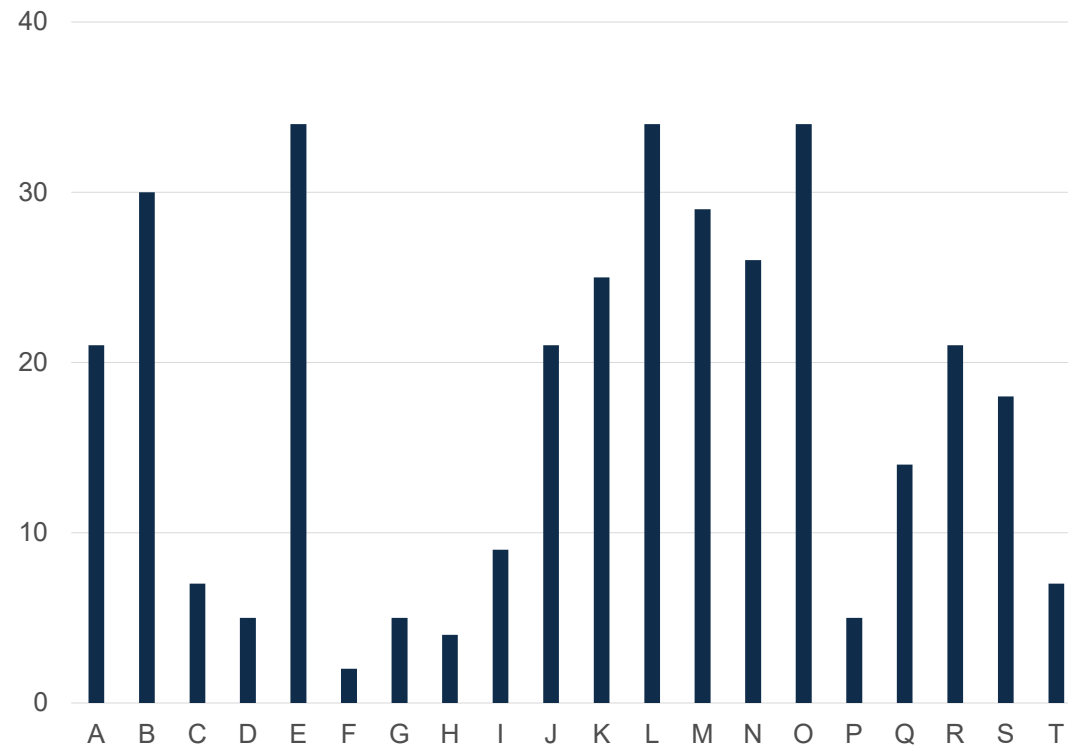
FY2022 FY2023 FY2024 FY2025 FY2026 FY2027 FY2028 FY2029 FY2030

2-2-9 | Active Pipelines for Antibody Drug at Large Pharmaceutical Companies

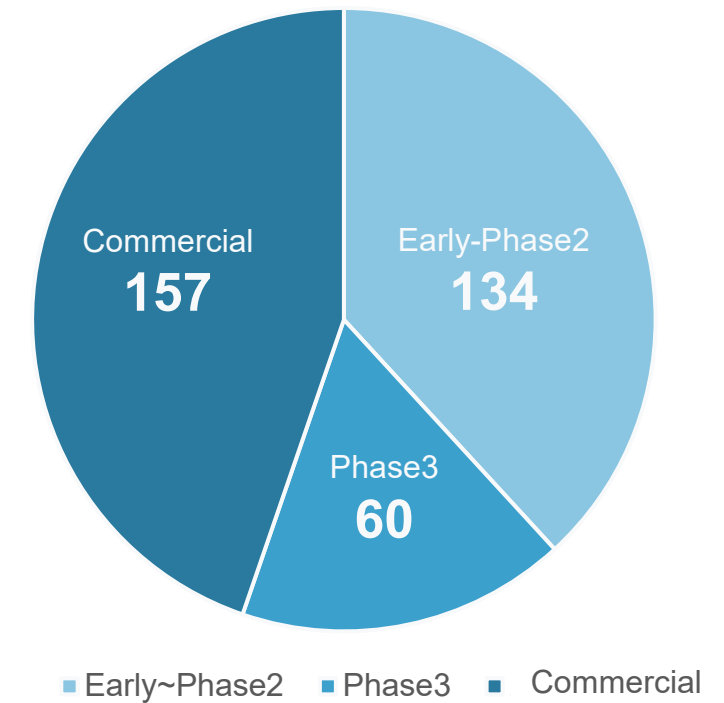
Large pharmaceutical companies have abundant pipelines for antibody drug in all clinical development stages. Fujifilm accelerates commercial negotiations by leveraging its strengths of End-to-End service capability.

Active pipelines of 20 large pharmaceuticals companies

Program Numbers by Companies(N=351)



Program Numbers by Clinical Development Stages(N=351)



*Data based on interview at business meeting

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2-3 | Cell and Gene therapies

Although there is stagnation in cell and gene therapies due to funding issue in biotech,
We continue to invest based on long-term market growth trend.

■ Bio CDMO ■ Life Sciences

Market Environment

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Our measures / responses

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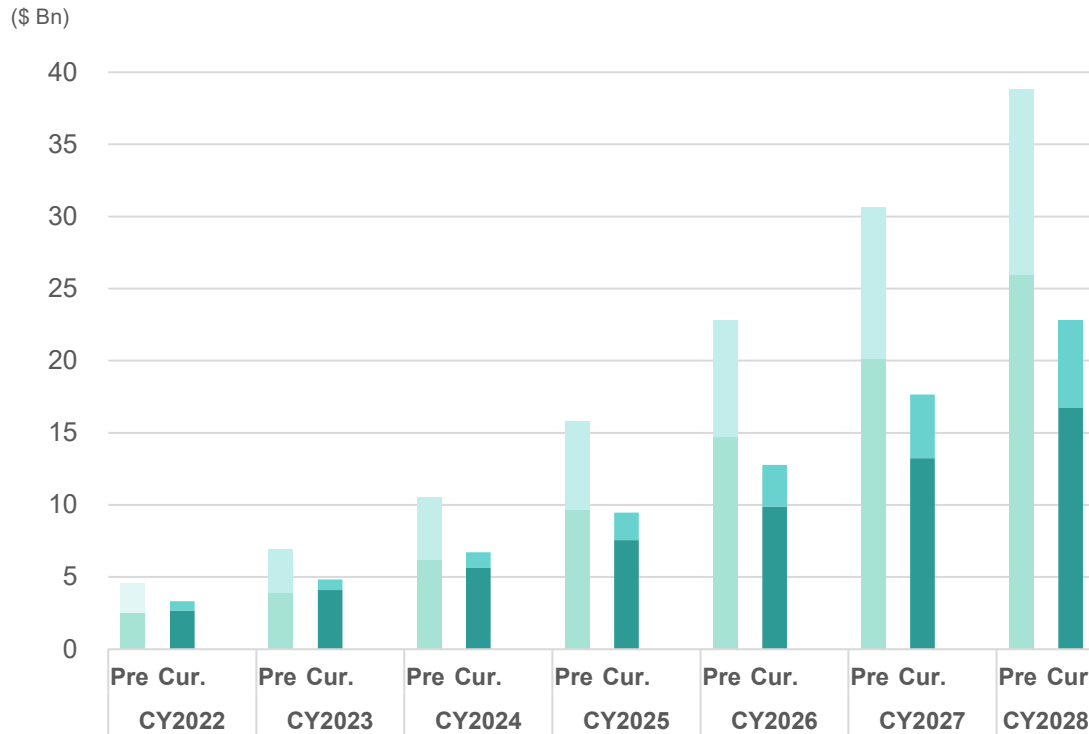


- | ■ Strengthen partnerships through manufacturing near customers by leveraging our geopolitical advantage of having a global footprint

2-3-1 | Market trend of Cell and Gene therapy

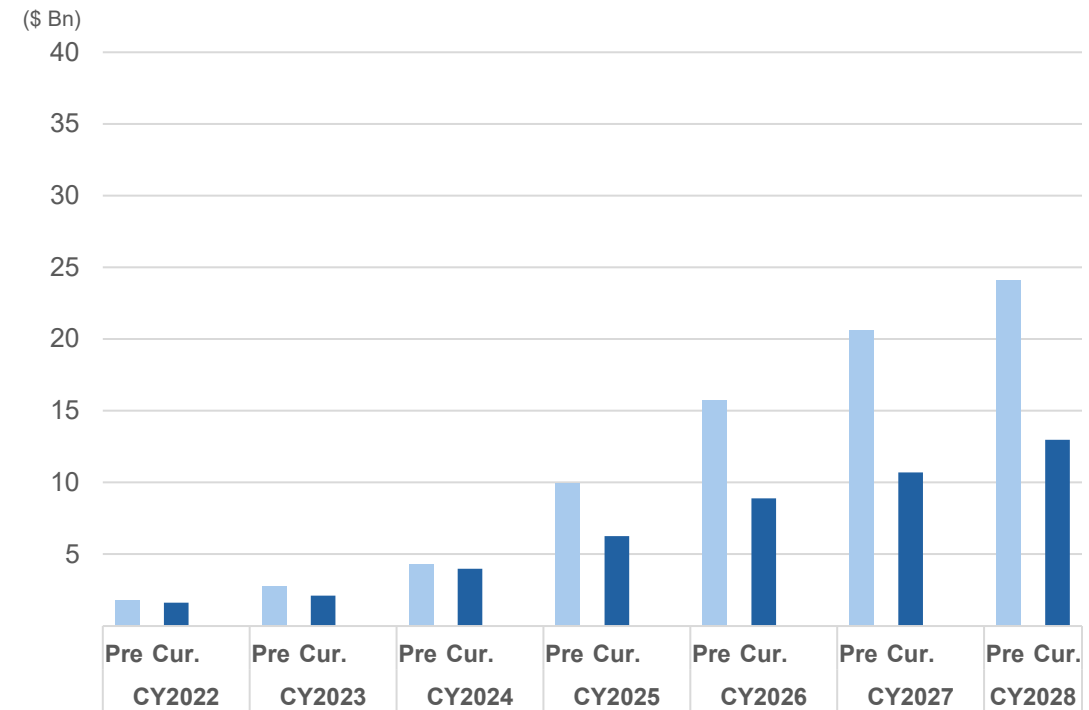
**Due to funding issue in biotech and clinical stagnation, market growth will be delayed compared to previous forecast (Cell therapy : delay by 1-2years, Gene therapy : delayed by over 2years)
However, it is anticipated that these fields will still experience high growth in the long term**

Market Trend Forecast compared vs previous year (As of Oct 2023 vs our Current estimation)



Cell Therapy (Others) | CAGR 2023-2028 : 46%

Cell Therapy (Gene-Modified) | CAGR 2023-2028 : 36%



Gene Therapy | CAGR 2023-2028 : 41%

2-3-2 | Cell Therapy: Investment in 2 sites in the US

Addressing the increasing demand for CDMO service for cell therapy

**Fujifilm to invest USD 200 Million
to Expand 2 sites in the US**

Double the capacity for cell therapy at Wisconsin site and California site

FUJIFILM



Wisconsin Site

Offering CDMO service for iPSC-derived cell therapy by leveraging the state-of-the-art iPSC-related technologies



California Site

Offering CDMO service for allogenic cell therapy such as donor-derived cell therapy by leveraging experience and track record of manufacturing commercialized pharmaceuticals and clinical drugs

2-3-3 | Challenges and Future Prospects of Cell Therapy

While patient-specific Autologous Cell Therapy (with patient's own cells) have been the predominant approach, there is a growing focus on Allogeneic CTs (with donor-derived cells or iPSCs). This shift is motivated by the potential for cost reduction and quicker processing times.

Challenges of Autologous Cell Therapy

**Patient-specific, tailor-made approach :
high cost/long lead time**

The process of “cell collection ~ cultivation ~ administration” lacks stability, leading to high costs. The long lead time makes it challenging to meet patients' needs in a timely manner.

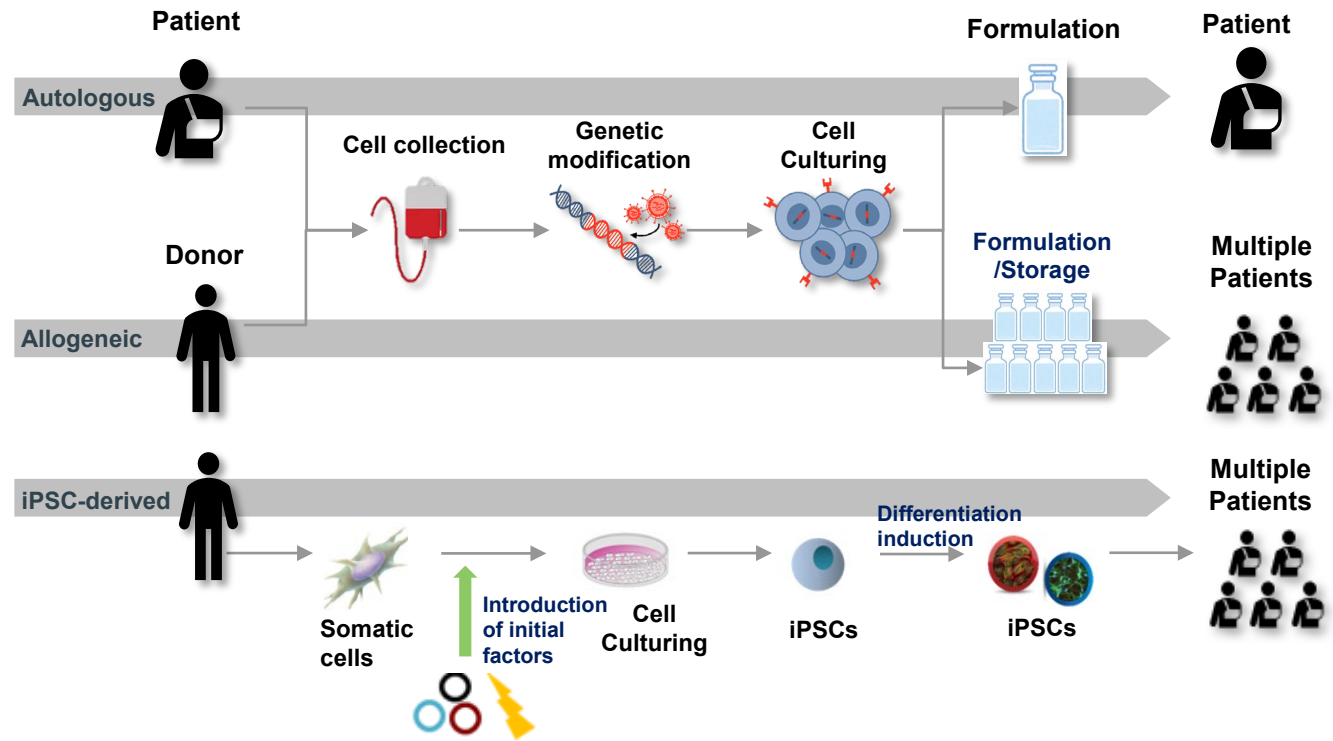


Breakthroughs in the Cell Therapy industry

Transition from tailor-made (autologous) to off-the-shelf (allogeneic) products

Shifting towards a manufacturing process that utilizes donor cells or iPS cells instead of patient cells, enabling greater stability and cost-effectiveness.

Manufacturing processes of Cell Therapy drugs (autologous vs allogeneic)



- **Benefits of utilizing allogeneic approaches:**
- **Shortened lead time** : Timely shipments to meet patients' needs achieved by standardization.
 - **Cost reduction** : Cost savings by treating multiple patients with a single donor cell.

2-3-4 | Investments Details of FCDI (Wisconsin Site) and FDB (California Site)



FUJIFILM

Name FUJIFILM Cellular Dynamics, Inc.

Location Madison, Wisconsin, US

Investment Details

- ✓ Expansion of process development laboratory and cGMP facility for cellular therapeutics (manufacturing clean rooms from 3 to 6)
- ✓ Development, production facility and warehousing of cells for drug development support

➔ **Expanding the capacity for cell therapy to double the current level**

Total Floor Area Approx. 175,000 sq. ft

Start of Construction November 2023

Operation Period 2026

Name FUJIFILM Diosynth Biotechnologies California, Inc.

Location Thousand Oaks, California, US

Investment Details

- ✓ Expansion of laboratory and GMP facilities for process development of cellular therapeutics (manufacturing clean rooms from 3 to 5)
- ✓ Remodeling of existing GMP facilities, expansion of warehouses, etc.

➔ **Expanding the capacity for cell therapy to double the current level**









Start of Construction 2024

Operation Period 2025



2-3-5 | Global Footprint

Reinforcing the global service offering for a wide range of modalities including the advanced therapeutics

Investment projects already announced as of Dec, 2023 *Without small molecules Figures in parentheses are the operation period of facilities under expansion.		North America					Europe		Asia
		RTP NC, US 	Collage Station TX, US 	Thousand Oaks CA, US 	Boston MA, US 	Holly Springs NC, US 	Madison Wisconsin, US 	Billingham UK 	Hillerød Denmark 
Antibody Drug	Large-Scale (=20,000L)					● (2025)		● (1 st : 2024) (2 nd : 2026)	
	Small-Medium Scale	●	●				● (2026)		● (2026)
Recombinant Protein		●					● (2028)		
Gene Therapy			●		● (2024)		● (2027)		
Cell Therapy				● (2025)		● (2026)			
Vaccine		●	●				●		● (2026)
Formulation			●	●		● (2025)		● (2024)	● (2026)
Assembly, Labeling & Packaging						● (2025)		● (2024)	● (2026)



Bio CDMO Business

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Wrap-up

2-4 | Supply Chain Management

Inventories piled up due to longer lead times during COVID-19, resulting in write-downs in the first half of FY2023. We are currently reinforcing our supply chain and inventory management operations.

■ Bio CDMO ■ Life Sciences

Market Environment

Impact on company

Our measures / responses

- Steady demand for conventional antibody drugs
- Progress in the development of next-generation antibody drugs (ADC etc.)



- Strong performance of antibody drugs manufacturing mainly at the Denmark site



- Smooth launch of a new large-scale facilities
- Boosting capabilities to next-gen antibody drugs (ADC, etc)
- Conversion of gene therapeutic tanks for antibody drugs manufacturing (Under consideration)

- Sharp downturn in funding of biotech
- Stagnant pipeline development and decline in the number of new clinical trials



- Stagnant development orders for gene therapeutics
- Sluggish demand for cells / reagents for drug discovery support



- | Temporarily slowing down investment in gene therapeutics
- | ■ Continuing to invest in cell therapies in anticipation for long-term market growth

- Piling up components and consumables, which were mass purchased amidst SCM confusion during the COVID-19



- | ■ Write-down for inventories which nearing the end of shelf life
- Decline in culture medium as a result of clients' inventory adjustment



- | ■ Reinforcement of supply chain management

- Review of suppliers and changes in SCM environment based on COVID experiences
- Growing significance of BCP



- | ■ Increased contracts orders as 2nd / 3rd site
- Acquiring new customers due to an increase in purchase from multiple suppliers.

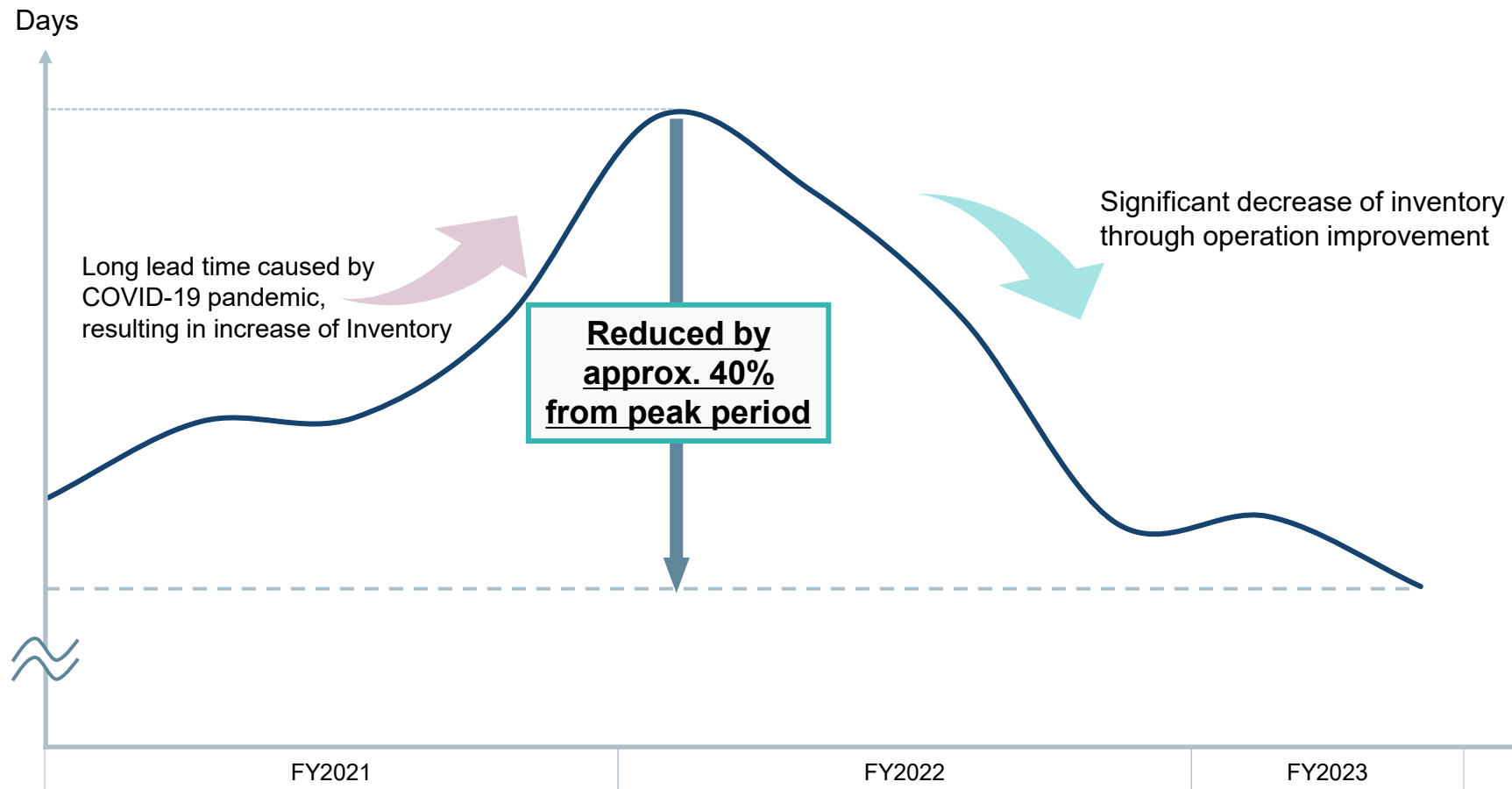


- | ■ Strengthen partnerships through manufacturing near customers by leveraging our geopolitical advantage of having a global footprint

2-4-1 | Inventory Management for Responding to the Risk of Market Volatility

Establish inventory management framework that can be flexible in response to market volatility and promoting inventory reduction while determining appropriate levels required for a stable supply.

Trend for Inventory Turnover Days of bio CDMO Business and Life Sciences Business



Bio CDMO Business

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Bio CDMO Business

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Overall Strategy

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Business Strategy for Antibody Drug

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Business Strategy for Cell & Gene Therapy

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Supply Chain Management

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Wrap-up

2-5 | Bio CDMO Business Growth Strategy

1

Expanding business with CDMO service for antibody drug as a growth driver

- Providing scalability for small-medium and large-scale manufacturing
- Offering End-to-End services from API production to formulation and packaging
- Dynamic capital investments in Europe and the US which close to client and market

2

Reinforcing service offerings for the advanced therapeutics with strong market potential

- Investing USD 200 million in Wisconsin and California sites in the US to expand CDMO business for allogenic cell therapies utilizing iPSC and donor-derived cells

3

Contributing to a timely and stable supply of pharmaceuticals as “The trusted Partner”

- Expanding capacity to meet growing demand
- Accumulating experiences, know-how and track record for highly efficient and stable manufacturing
- Building up experience and insight on dealing with various regulations

Life Sciences Business

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Overview

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Bio CDMO Business

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Life Sciences Business

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Technological Advantages

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Environmental Strategy

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Summary

Yutaka Yamaguchi

- 
- Apr. 1990 ○ Joined FUJI PHOTO FILM Co., Ltd.
- Apr. 2014 ○ General Manager, Life Science Business Division (Currently Consumer Healthcare Business Div.)
- Jun. 2018 ○ CEO, FUJIFILM Irvine Scientific, Inc.
GM, LS Strategic Business Office, FUJIFILM Holdings America Corporation
- Apr. 2021 ○ GM, Life Sciences Business Division, FUJIFILM Corporation
CEO, FUJIFILM Irvine Scientific, Inc.
GM, LS Strategic Business Office, FUJIFILM Holdings America Corporation
- Jun. 2022 ○ Corporate Vice President, FUJIFILM Corporation
General Manager, Life Sciences Business Division
Chairman & CEO, FUJIFILM Irvine Scientific, Inc.
- Jun. 2023 ○ **Corporate Vice President, FUJIFILM Corporation (Based in California,US)**
Senior Deputy General Manager, Life Sciences Strategy Headquarters
General Manager, Life Sciences Business Division
CEO, FUJIFILM Irvine Scientific, Inc.**

Life Sciences Business

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Life Sciences Business

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Life Sciences Business Overview

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iPSC Cell Therapy R&D Support

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Drug Discovery & Manufacturing Support

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Wrap-up

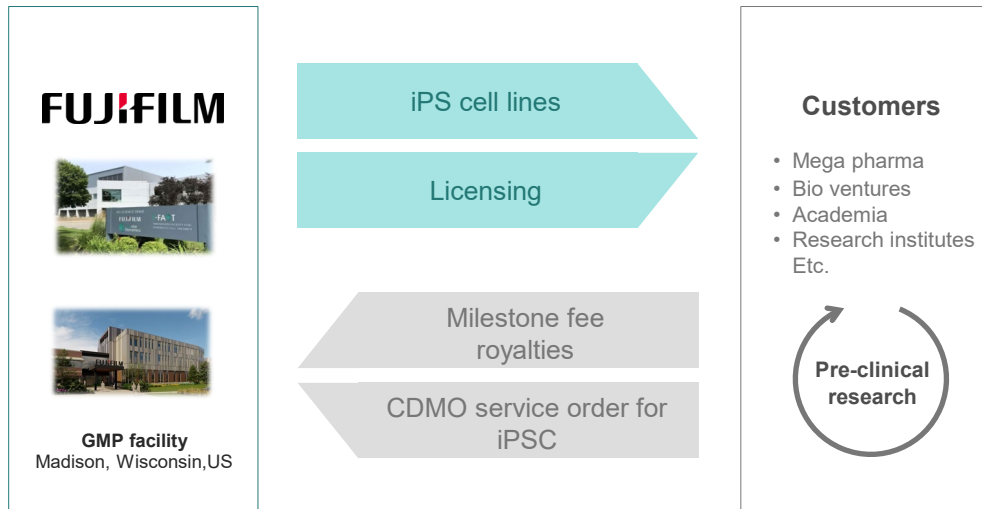
3-1-1 | Life Science Business overview

Providing solutions in the areas of iPSC cell therapy as well as drug discovery and manufacturing to contribute to addressing unmet medical needs

Cell Therapy

Supporting R&D on iPSC cell therapies

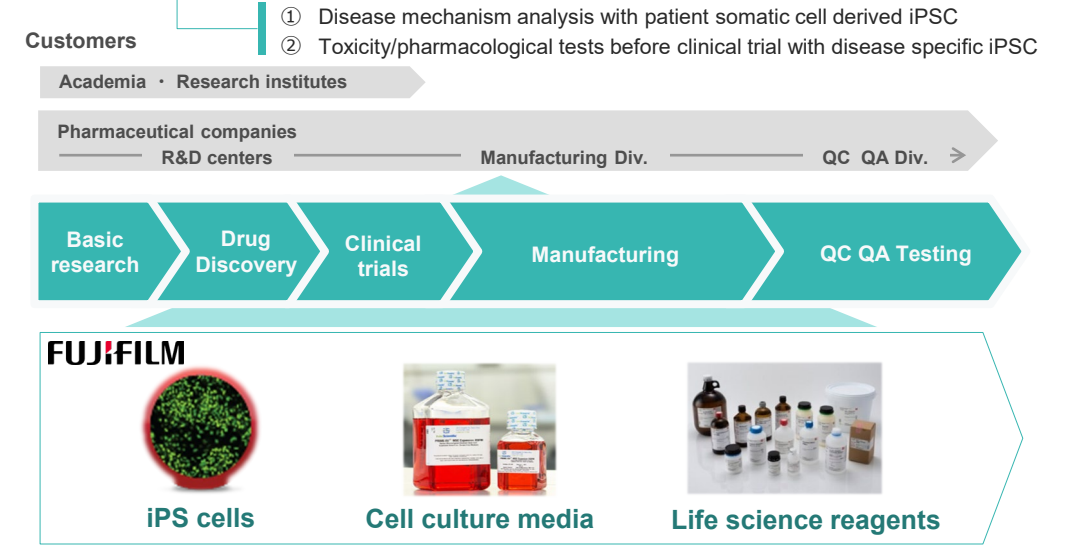
Utilizing iPSC technology and know-how, we facilitate support for iPSC cell therapy R&D by providing iPS cell lines and licensing, which also leads to future iPSC CDMO business.



Drug Discovery

Supporting drug discovery R&D and manufacturing

Across a broad scope from basic research to manufacturing and safety/quality tests, we provide a diverse range of products and services such as iPS cells, cell culture media, and life science reagents tailored to customer needs



3-1-2 | Mid- to long Term Target

After Covid-19 demand recoil and inventory adjustment across the market in FY2022, signs of recovery emerged in 2H of FY2023. We anticipate continuous market growth for media, cells, and reagents, and maintain our medium and long-term targets

Target

① Revenue FY2025: ¥100Bn, FY2030: ¥200Bn

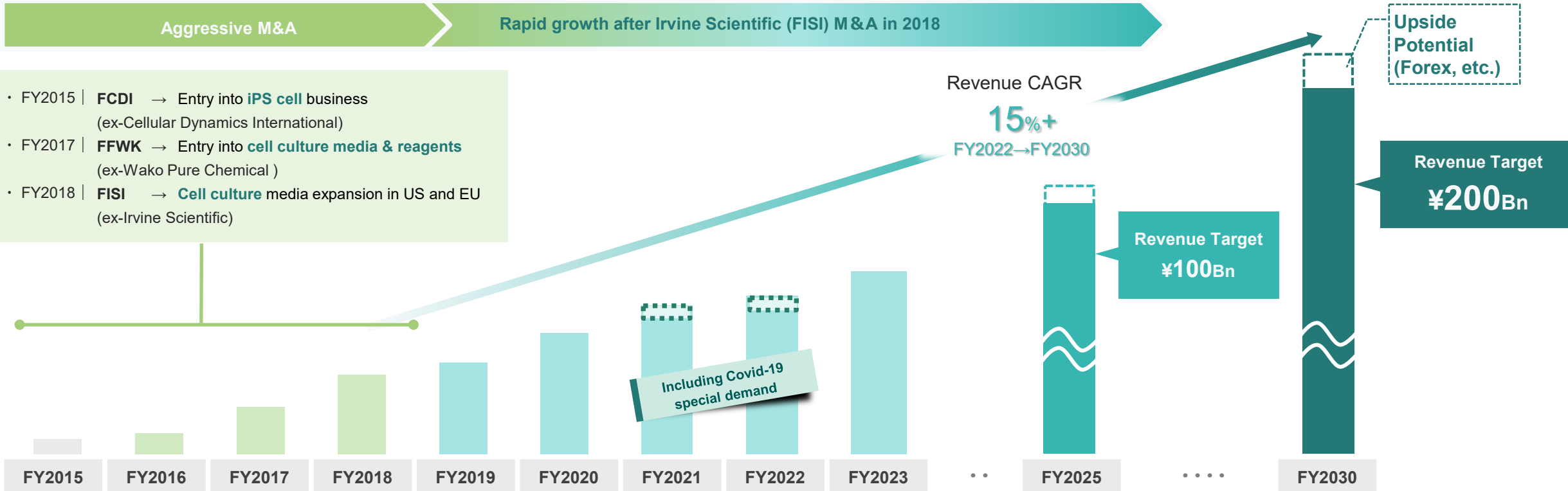
② FY2022-2030 CAGR 15%+*

(*) Higher than industry avg. of 11% (in-house research)

Aggressive M&A

Rapid growth after Irvine Scientific (FISI) M&A in 2018

- FY2015 | **FCDI** → Entry into **iPS cell** business (ex-Cellular Dynamics International)
- FY2017 | **FFWK** → Entry into **cell culture media & reagents** (ex-Wako Pure Chemical)
- FY2018 | **FISI** → **Cell culture** media expansion in US and EU (ex-Irvine Scientific)



*The data for FY20 and prior realigned based on the current life science business.

*Japan Tissue Engineering (J-TEC) not included.

*Only LS reagent business included for FUJIFILM Wako Pure chemical.

Life Sciences Business

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Life Sciences Business

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Life Sciences Business Overview

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iPSC Cell Therapy R&D Support

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Drug Discovery & Manufacturing Support







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Wrap-up

3-2-1 | iPSC Cell Therapy R&D Support : iPS Cell Lines & Licensing

Support R&D of cell therapy by actively providing iPS cell lines and IP licensing to developers.
Acquire milestone and license fees in line with the progress of development and link it to CDMO contract services to build a stable business foundation.

Main Licensees

	Licensee	Disease Area	Status
New 1	 novo nordisk®	Chronic diseases	Pre-clinical
New 2	 IASO BIOTHERAPEUTICS (U.S.)	Cancer	Pre-clinical
3	 CENTURY THERAPEUTICS	Cancer, auto-immune/ inflammatory diseases	<ul style="list-style-type: none"> • Auto-immune/inflammatory diseases : added to the license field (Sep. 2023) , IND approved (Dec.2023) • Cancer: Clinical trial Ph1 ➔ CDMO: FCDI supplied cells for the clinical trial
4	 cynata therapeutics	GvHD, DFU, osteoarthritis, renal transplant	<ul style="list-style-type: none"> • PhI-III clinical trials for several diseases ➔ CDMO: FCDI has a contract for clinical /commercial manufacturing
5	 Ryne Bio	Parkinson's disease	<ul style="list-style-type: none"> • Pre-clinical with FCDI's therapy program(IND within FY2023) ➔ CDMO : FCDI provides process development /manufacturing
6	 Sana Biotechnology®	N/A	Pre-Clinical
7	U.S. Bio-Venture	Cancer	Pre-Clinical
8	Japanese Bio-Venture	N/A	Pre-clinical
9	U.S. Bio-Venture	Infection, Cancer	Pre-Clinical

Milestone fees Royalties
CDMO business

Life Sciences Business

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Life Sciences Business

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Life Sciences Business Overview

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iPSC Cell Therapy R&D Support

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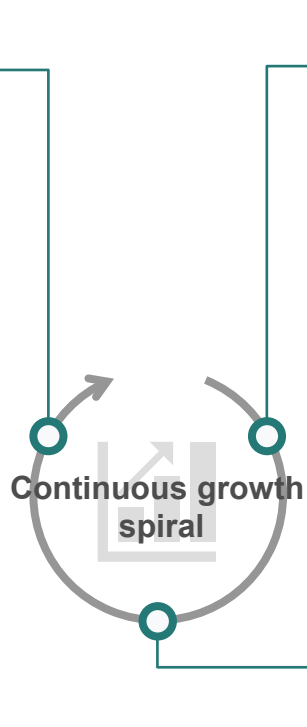
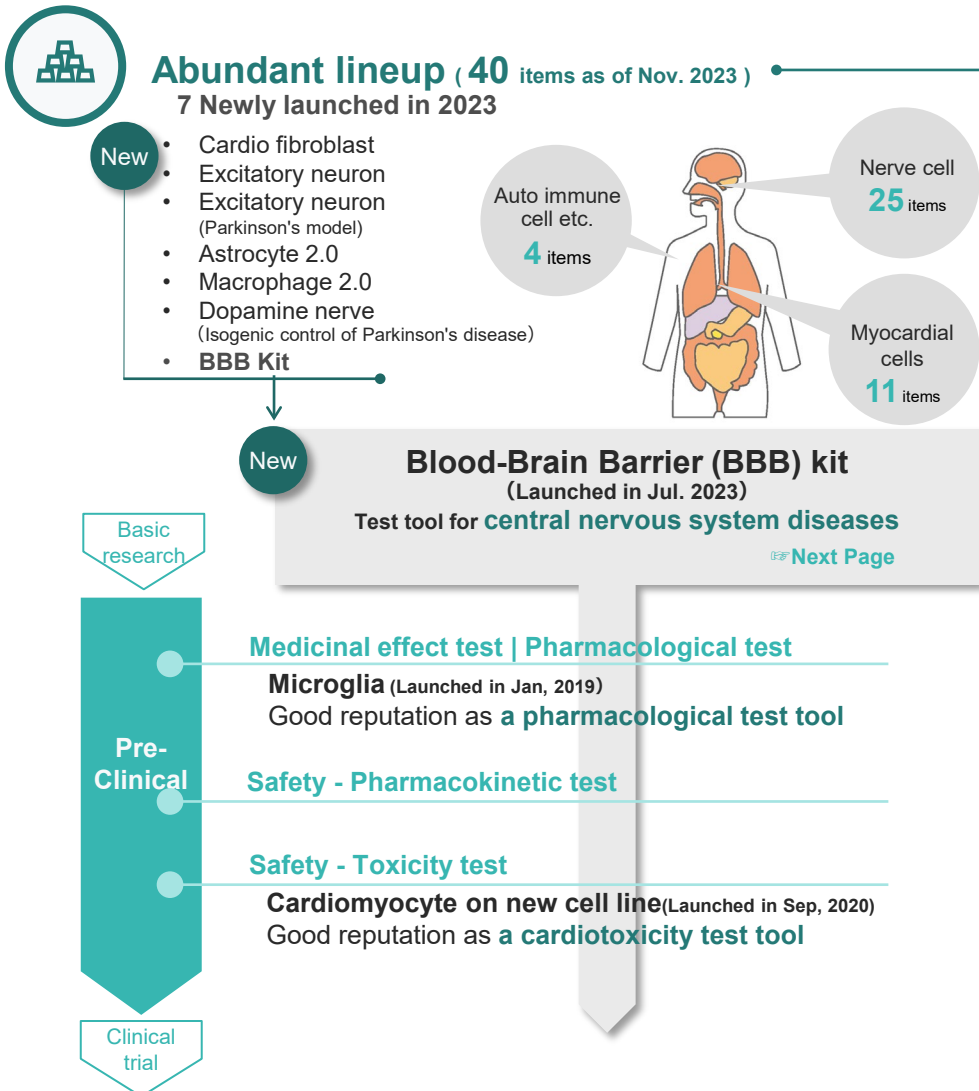
Drug Discovery & Manufacturing Support

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Wrap-up

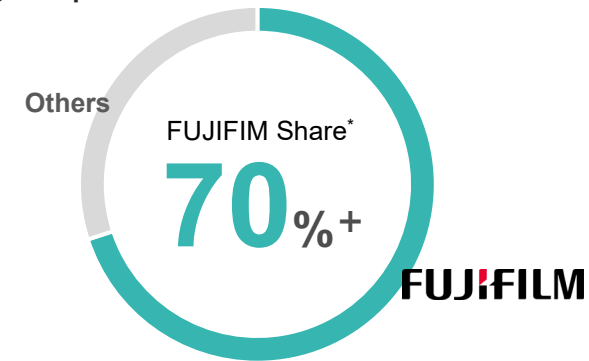
3-3-1 | Drug Discovery Support with iPSC products

We have a 70% market share of iPSC-derived cells for drug discovery, and over 300 research paper citations. Continue to expand lineup to build further trust with customers to realize a continuous growth spiral



Top runner with 70% market share

Over 400 customers including top 10 mega pharma in Japan, Europe and US



*Share of demand for iPSC-derived cells purchased from 3rd party (in-house research)



Over 300 research paper citation

- Science Translational Medicine
- Journal of immunology Research
- Nature communications
- Advanced Biology
- Nature Methods
- Nature Biotechnology
- Autophagy
- Immunity
- Stem Cell Reports
- Advanced Functional Materials
- npj Regenerative Medicine etc.

3-3-2 | Drug Discovery Support with iPSC products : Blood-Brain Barrier (BBB) Kit

Blood-Brain Barrier

Launch the World's first iPSC-derived BBB kit for drug discovery capable of duplicating human BBB function in vitro
Contributes cost savings & more efficient R&D to discover drugs for dementia / Parkinson's disease

What is BBB (Blood - Brain Barrier) ?

3 functions to maintain brain environment

- (1) Delivery : Deliver oxygen/nutrients to brain from blood vessels
- (2) Discharge : Discharge unnecessary substances into blood vessels
- (3) **Barrier** : Prevent intrusion of hazardous substances

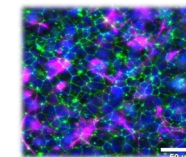


Barrier : Prevent intrusion of hazardous substances

R&D needs

Raise accuracy of passability tests by using human-derived cells

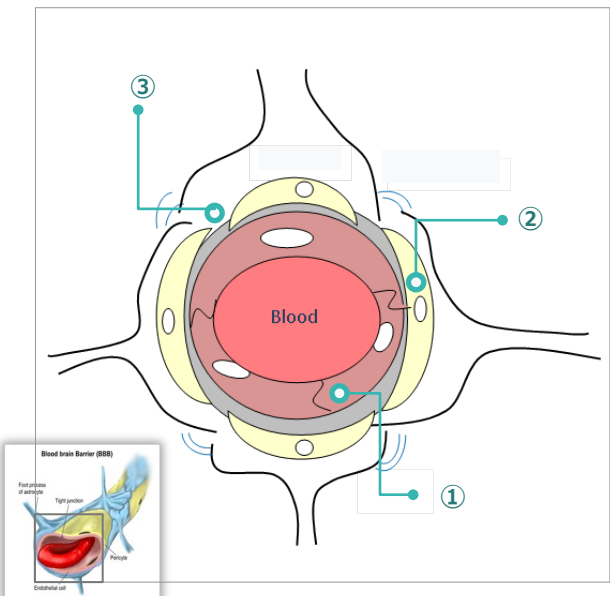
Speed up of R&D process



iPSC-derived cell kit for drug discovery
[iCell® Blood-Brain Barrier Isogenic Kit]

World's first

3 constituent elements of BBB



- | | | |
|---|-----------|--|
| ① | BMEC | |
| ② | Pericyte | |
| ③ | Astrocyte | |

R&D support for new drugs capable of being efficiently delivered to brain through BBB to treat central nervous system diseases such as dementia and Parkinson's disease

3-3-3 | Cell Culture Media : Bio Production Global Market

We are focusing on Bio Production (BP) media, a growing market with a CAGR of 10% +. We aim to achieve revenue of ¥100Bn and top market share of 30%+ by FY2030.

BP Media: Market forecast

(In-house research)

BP (Bio production) Serum free media* CAGR

FY2022-2030
10%+

*Serum free media

Safer, more productive, and higher operability than animal-derived serum media due to the chemically-defined ingredients. Customers use serum free media for commercial production.



BP Media Market share forecast

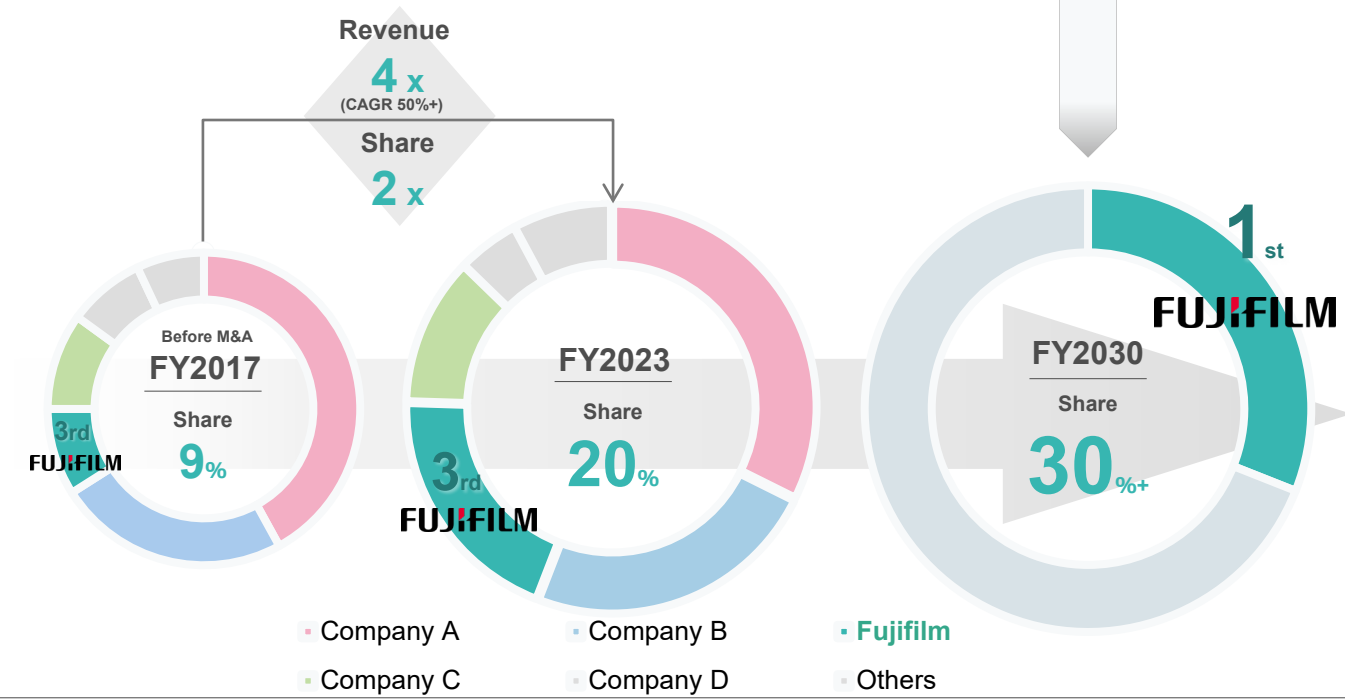
(In-house research)

FY2030 Target



Revenue
¥100 Bn

Share
30%



3-3-4 | Cell Culture Media : Our strength

With manufacturing sites near customers and a global structure providing identical quality and service, We have partnered with a wide variety of customers from biotech and academia to major pharmaceutical companies

R&D

Manufacturing

Sales · Services








Handling processes from R&D to manufacturing, working together as a partner globally to provide products and services meeting customers' needs

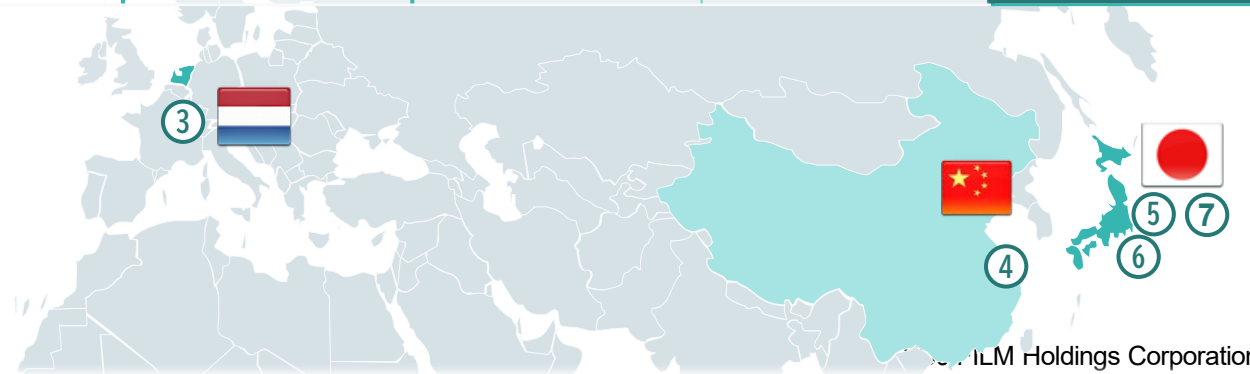
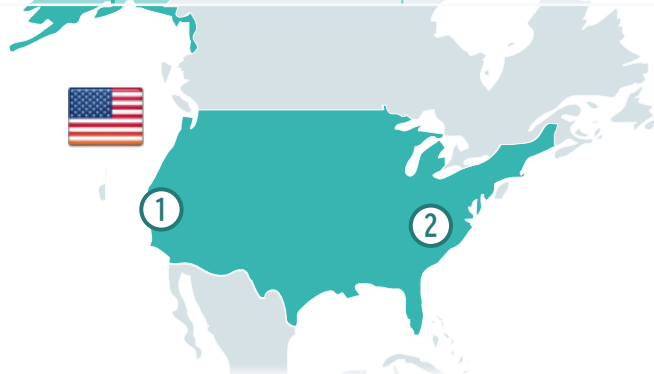
- | | | |
|--|--|--|
| <ul style="list-style-type: none"> ■ Advanced media portfolio ■ Media development know-how with more than 50 years experience ■ Ability to customize media to meet customer needs ■ Ability to optimize media in collaboration with FCDI (iPS cells) and FDB (culture processes) | <ul style="list-style-type: none"> ■ Stable supply meeting growing demand with timely investment in 3 global manufacturing locations in US, EU, and Japan ■ Maintain equivalent media at each manufacturing sites with integrated management of equipment, raw materials, SOP, etc. ■ High quality media produced at GMP facility ■ QC & QA system using advanced analytical technology ■ Steady long-term relationships with suppliers ■ Various regulatory compliance achievements | <ul style="list-style-type: none"> ■ 「One stop shop」 sales system with combination of FCDI (iPSC) and FFWK (reagents) ■ Steady supply through global sales network ■ Consultation and technical support by experienced technical staff |
|--|--|--|

We identify customer needs timely and accurately to develop better media for continuous evolution

3-3-4 | Cell Culture Media : Global Footprint

Continuous investment in US, Europe and Japan to expand manufacturing sites close to customers. To the rapid growing Asian market, establish a new site in Kanagawa with subsidies from Japanese government.

As of Dec. 2023	North America		Europe	China	Japan		
	Santa Ana CA, US  (2018 M&A)	RTP NC, US  (2026)	Tirburg Netherlands  (2021)	New District Suzhou  (2022)	Saitama  (2018 M&A)	Aichi  (2017M&A)	Kanagawa  (2027)
(Services since...)	(2018 M&A)	(2026)	(2021)	(2022)	(2018 M&A)	(2017M&A)	(2027)
Main market	West coast US	East coast US	Europe	-	Japan & Korea	Japan & Korea	Japan & Korea & China
Factory: powder (Maximum capacity)	● (1,200t / FY23)	● (800t / FY30)	● (320t / FY23)	-	● (90t / FY23)	● (100t / FY24)	● (500t / FY27)
Factory: liquid (Maximum capacity)	● (1,200kL / FY23)	● (3,300kL / FY30)	● (470kL / FY23)	-	-	● (720kL / FY23)	-
Customized service	●	-	-	●	●	-	-



Life Sciences Business

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Life Sciences Business

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iPSC Cell Therapy R&D Support

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Drug Discovery & Manufacturing Support

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Wrap-up

3-4 | Growth Strategy

1

Expand iPSC cell therapy R&D support business

Establish recurring business model for continuous growth by offering iPS cell lines and IP licensing, which can further lead to CDMO services at GMP facility (process development and CMO manufacturing)

2

Expand drug discovery and manufacturing support business

By leveraging our human iPSC for drug screening and pre-clinical testing, we promote Combined solutions (Cell/Media/Reagents) for pharmaceuticals and academia.

3

Growth of cell culture media business

As a partner to customers, we support from basic research to commercial manufacturing on a global basis. Aim to win a top market share* in FY2030 by providing of products and services to meet customers needs.

*serum free media for bio production

Technological Advantages

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Environmental Strategy

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Summary

Takeshi Yamamoto

- 
- Apr. 1991 Joined Fuji Photo Film Co., Ltd.
 - Mar. 2018 General Manager, Bioscience & Technology Development center, Research & Development Management Headquarters
 - Apr. 2019 President & CEO, FUJIFILM Cellular Dynamics, Inc.
 - Apr, 2021 President & CEO, FUJIFILM Cellular Dynamics, Inc.
Deputy General Manager, Life Sciences Business Div.
 - Jun, 2022 General Manager, Bio Science & Engineering Laboratories
 - Jun, 2023** **FUJIFILM Corporation Corporate Vice President**
Deputy General Manager, Life Sciences Strategy Headquarters
General Manager, Bio Science & Engineering Laboratories

Technological Advantages

4

Technological Advantages

4-1

Research Organization in Life Science Field

4-2

Antibody Production

4-3

Next-generation Modalities

4-1 | Research Organization in Life Science Field

The Bio Science & Engineering Research Laboratory(BSEL) serves as the core research institute in Life Science field, leveraging the technology cultivated photographic film business

Bio CDMO Business




US/Europe/Japan




BioScience & Engineering laboratory(BSEL)


Kaisei



Amagasaki



Toyama





Life Sciences Business

Cell (Drug discovery)



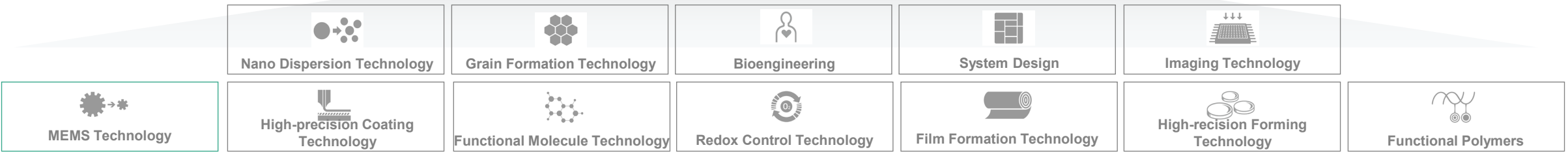
FCDI(US) | BSEL US

Media



FISI(US/Europe/Japan)

Core technology cultivated through our original photographic film business



Technological Advantages

4

Technological Advantages

4-1

Research Organization in Life Science Field

4-2

Antibody Production

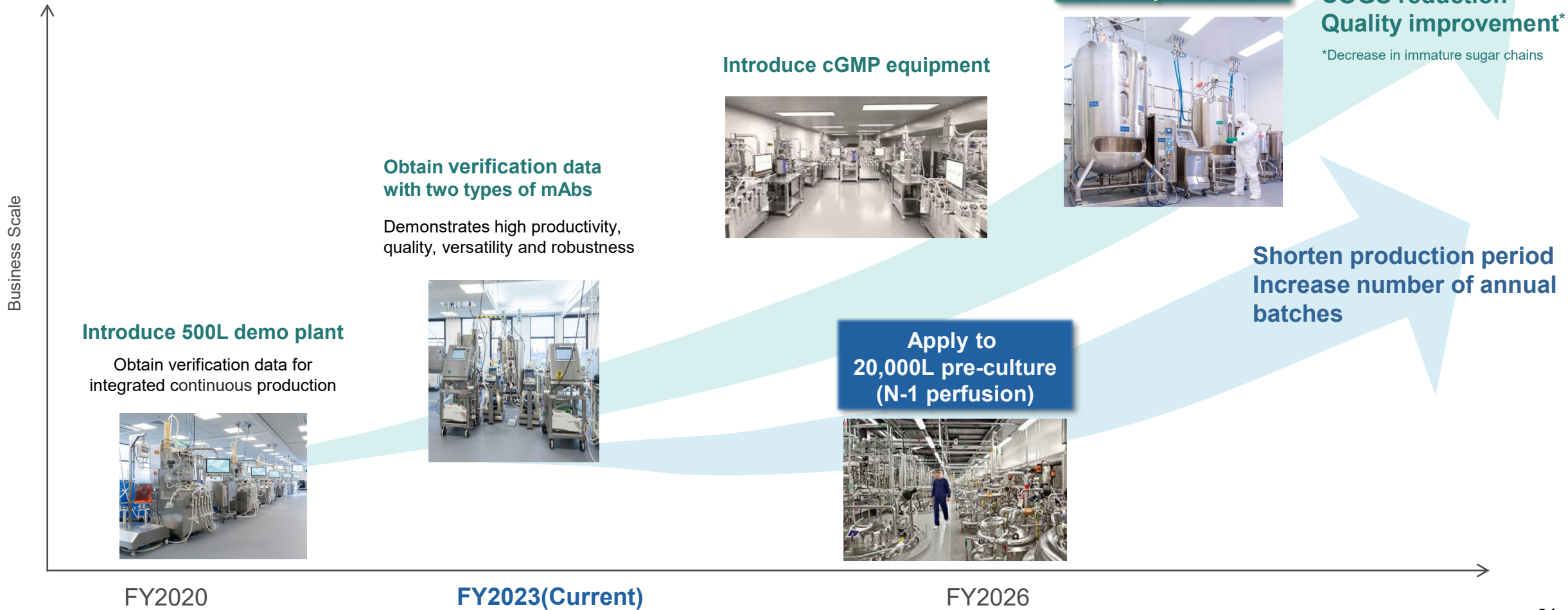
4-3

Next-generation Modalities

4-2-1 | Continuous Production System : Roadmap

Constructing GMP production facilities with a capacity of 2,000L in the US and the UK towards implementing the industry's first continuous production system. This will also be able to apply to pre-culture process (N-1 perfusion) to increase further productivity.

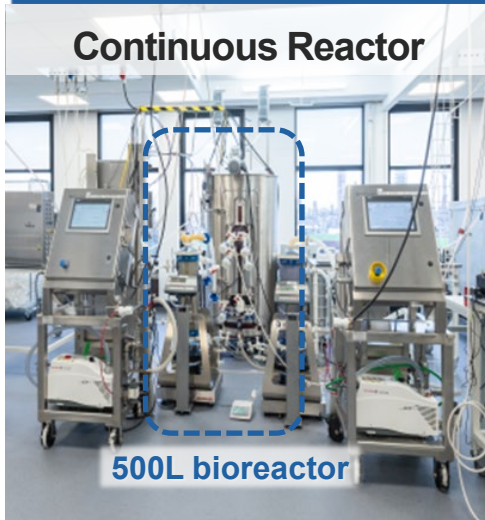
Developmental Roadmap



4-2-2 | Continuous Production System : Development Status

We succeeded to demonstrate continuous culture with the industry top level of cell density (120Mcells/ml) and continuous operation period (40days) at 500L demo run.

Business negotiations with clients are underway based on these achievements.

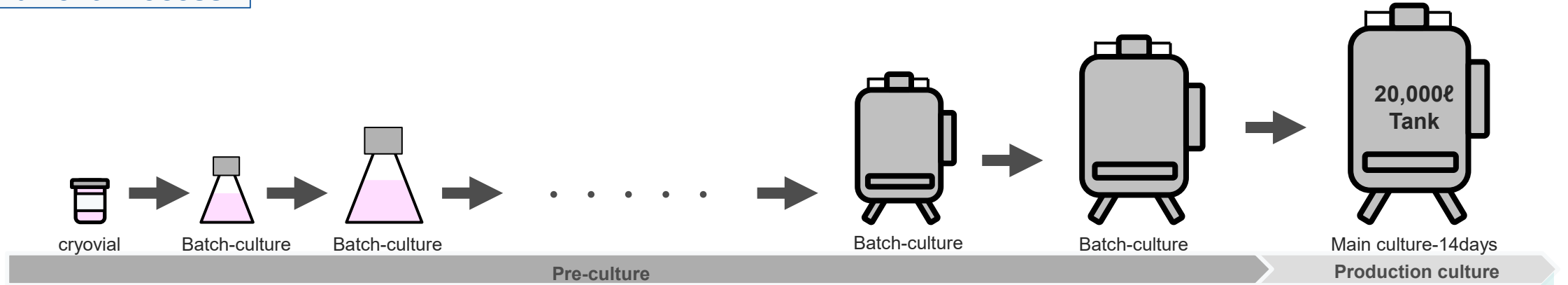


		CDMO & Equipment manufacturer (According to our research)				
		FUJIFILM	Lonza	WuXi Biologics Global Solution Provider	ThermoFisher SCIENTIFIC	SAMSUNG BIOLOGICS
Continuous culture	Cell titer	120Mcells/ml		~100 Mcells/ml	120 Mcells/ml	
	Scale	500L ➔ 2,000L (on going)	Started development of small scale	40L	500L	
	Culture period	40days~		25days	40days~	No info.
Continuous purification		Realize whole continuous process ➔ 2,000L scale is also available	No info.	Continuous Purification on 50 L	No info.	

4-2-3 | Application of Continuous Technology to Large Scale (20,000L) Manufacturing

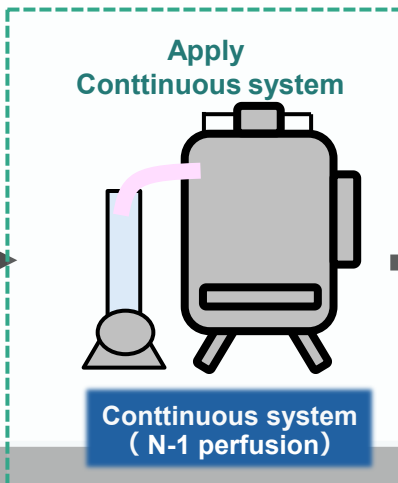
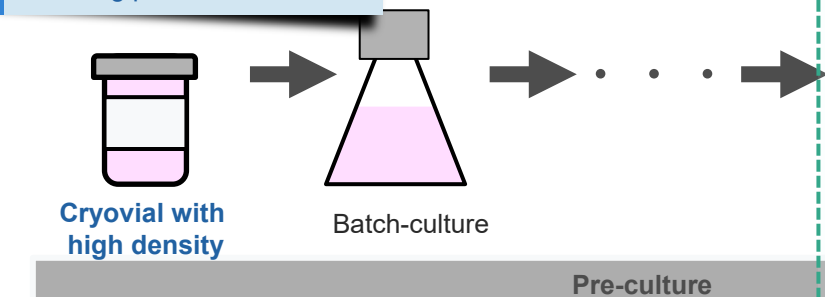
Applying continuous culture technology to the pre-culture process in a 20,000L large culture tank, which enables to improve yield and reduce cost. This technology will be deployed in new facilities at Denmark and NC in US

Current Process

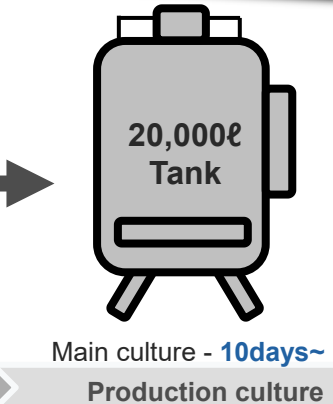


Novel Process

Preparing high density of cells with using perfusion



Seeding pre-densified cells in continuous culture
⇒ Boost antibody yield with increasing initial cell number



Benefits

Antibody yield/batch

Up to **30%** improvement

- *If operated with the same yield,
- Shorten the production period (up to 30% reduction)
- Increase the number of batches per year (up to 20% increase).

Technological Advantages

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Technological Advantages

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Research Organization in Life Science Field

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Antibody Production

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Next-generation Modalities

4-3-1 | Next-generation Biopharmaceuticals

We are currently developing innovative production technology for the future growth markets of “Novel antibody areas such as ADC and bispecific antibodies”, “Advanced therapies such as gene therapy and cell therapy”

			Fujifilm	Competitor
Antibody (mammalian culture)	Productivity	mAb	~10g/L	3~8g/L
		BiAb	~5g/L	1~2g/L
		Fc-fusion	1-2g/L (*pool)	1g/L (*pool)
	Conjugation	ADC	Developing conjugate technology	—
New	VGT (AAV)	Productivity	Flow-type gene transfection → 1.0×10^{13} vg/mL (×100)	1.0×10^{11} vg/mL
New	CT (Primary/iPSC)	Productivity	3D culture for iPSC and CAR-T → 10×10^9 cells/batch (10L)	~ 10×10^9 cells/batch
New	Nucleic Acid (mRNA/LNP)	Productivity Formulation Design	Unique ionized lipid library Scale up process	—

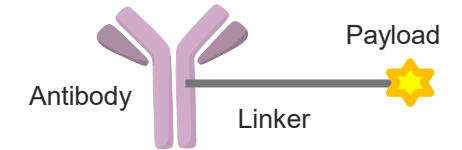
(In house research)

4-3-2 | ADC : Providing Services Utilizing Organic Synthesis Technology

In response to the rapidly expanding and diversifying ADC* market, we have begun developing conjugate technology that leverages our strengths in organic synthesis and analysis technology.
Scheduled to start providing end-to-end services from 2026 (Japan)

* **ADC**
(Antibody Drug Conjugate)

A biopharmaceutical that is a “conjugate” of an “antibody” and a “payload” using a “linker”



Current issues in ADC manufacturing

Issue 1

Non-uniform quality caused difficulty to control payload conjugation



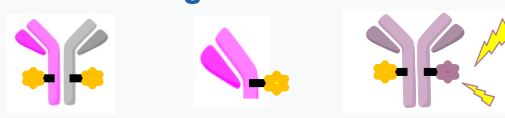
Technology development utilizing our organic synthesis and analysis technologies

Uniform quality



Issue 2

Immature conjugation technologies for next generation antibody



ADC for bispecific antibody

ADC for antibody fragment

Conjugation to dual payload

Our ADC contract manufacturing service (Sequential introduction)

Start End-to-End services at our domestic bases from FY2026.
In addition, we will build our own conjugate technology and expand our services eventually.

	Antibody Production	Synthesis linker and payload	Conjugate reaction
Global CDMO bases	✓	Expand	Expand
Domestic CDMO bases	Start service from FY2026	✓	Launched Lab-scale service Start cGMP service from FY2026

4-3-3 | VGT : Industry's First Continuous Flow Gene Transfer Device

We have developed a “continuous flow gene transfer device” for gene transfection process which is the bottleneck in AAV vector production, that can efficiently introduce genes into high-density cells (first in the industry)
This achieved 100 times more production for AAV vector than conventional methods

Production flow for AAV

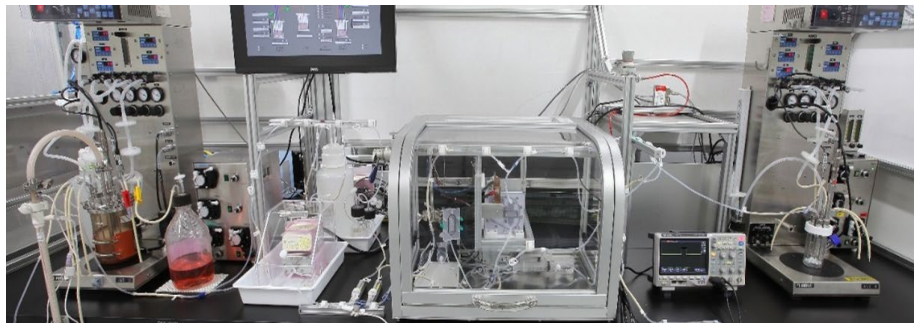
Cell Culture → **Gene Transfer** → Virus Production → Harvest & Purification

Conventional method | AAV gene is encapsulated in a special reagent. but...
Issue-1 | Low AAV productivity due to inefficient introduction transfection
Issue-2 | Usage of a large amount of AAV gene brings high cost

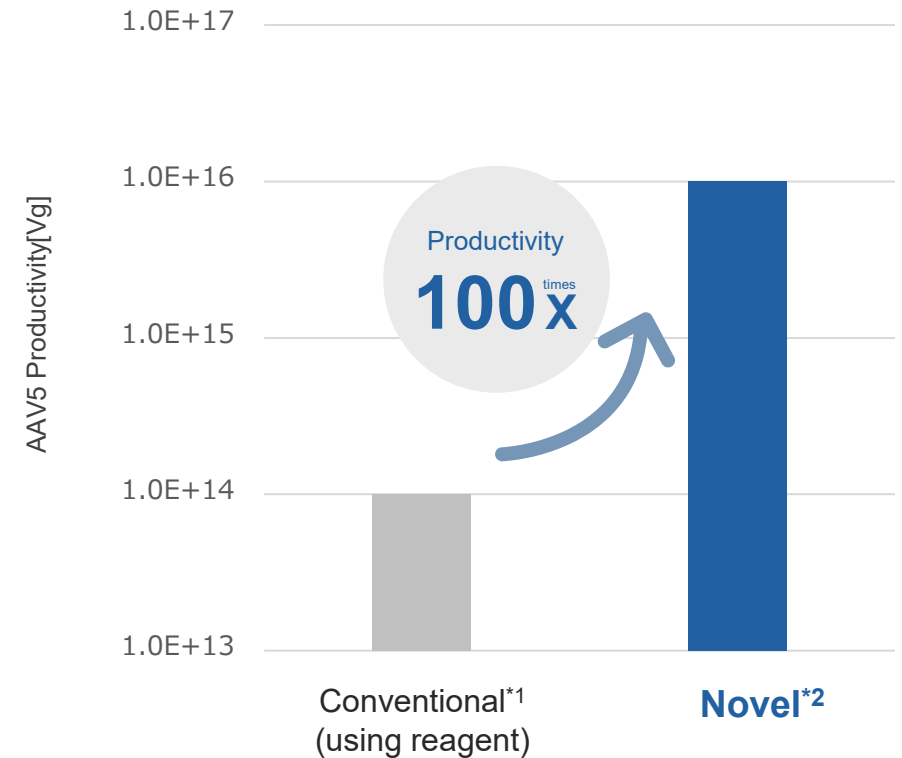
Our original methods

Developed a technology (continuous flow gene transfer device) that inserts AAV genes with high efficiency by applying voltage while pumping cell fluid.

⇒ Demonstration at customer sites planned for the first half of next year



Continuous flow gene transfer device

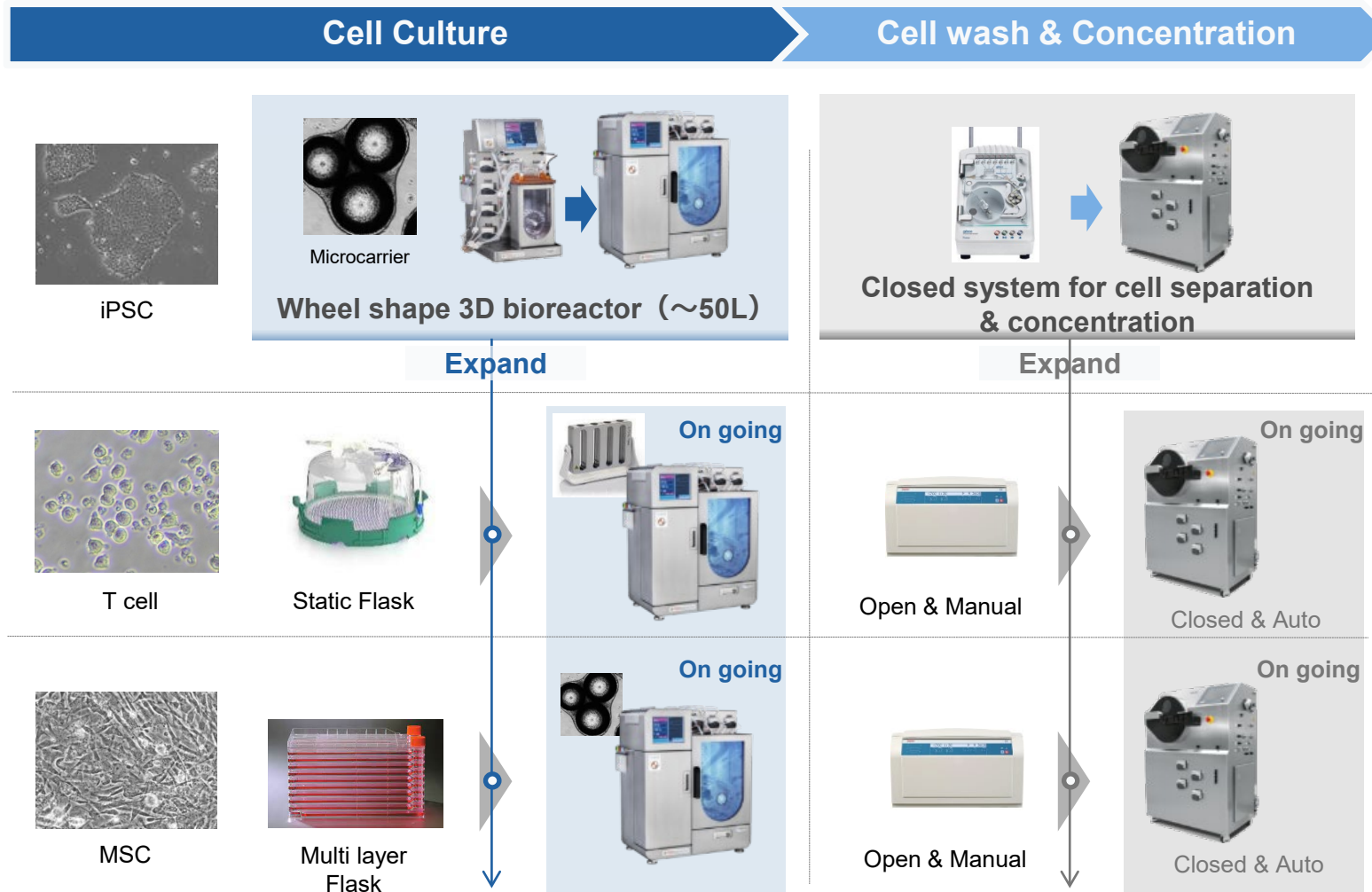


*1: 1batch

*2: integrated for 30days

4-3-4 | CT : Manufacturing Platform (iPSC/CAR-T/MSC)

We have competitive production technology and clinical manufacturing experience in multiple modalities such as iPSC, CAR-T and mesenchymal stem cells(MSC). By leveraging these knowledge and technologies, we aim to develop a “Cell therapy platform for commercial production”



Track Record

(According to our research)

iPSC
 Established closed production process and applied it to clinical manufacturing.
Demonstrated 1.0×10^9 cells/batch in 10L scale (industry leading)※
 *Present at ISSCR2021

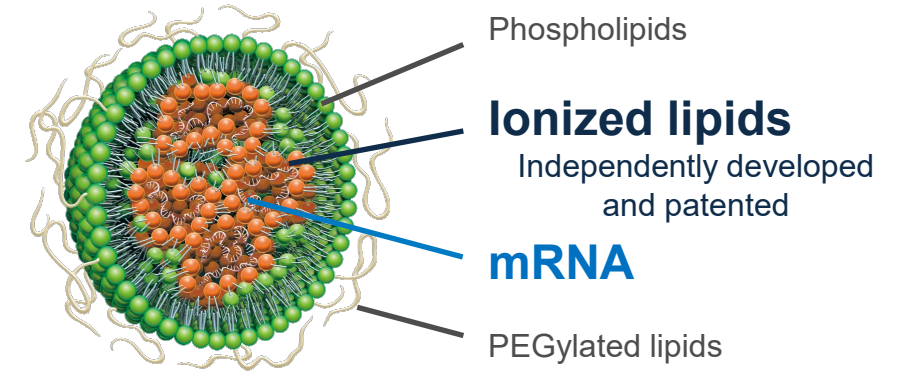
CAR-T
FDBC is promoting contract manufacturing for CAR-T product.
 Succeeded in scaling up to 3L with utilizing iPSC knowledges※
 * Present at ASCGT2023

MSC
Established production process for Ph III clinical trial in our pipeline (FF-31501).
We are developing mass production processes leveraged with iPSC knowledges.

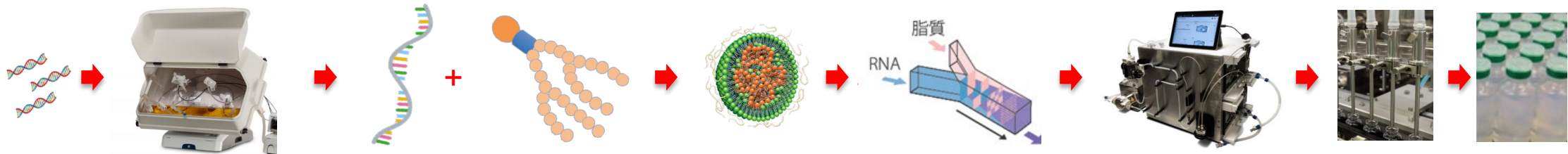
4-3-5 | mRNA/LNP : Expansion of New modalities

Started end-to-end CDMO service from production of mRNA* drug substance to LNP formulation** (Japan)
 We provide our uniquely developed ionized lipid materials and provide precise LNP formulation design services to support customer development.

- * **mRNA substance** (messenger RNA) A nucleic acid molecule that encodes a target protein. Artificially synthesized and used as a drug substance.
- ** **LNP formulation** The process of formulating pharmaceuticals by encapsulating mRNA in lipid nanoparticles (LNPs)



Cross section of LNP



High purity mRNA synthesis

LNP design using **unique ionized lipids**
 (requirements: sustained release, low toxicity, stability, etc.)

Joint Research with MIT(Since 2017)

Scale-up using microchannels

Clinical manufacturing

Track record of mRNA vaccine clinical manufacturing for VLP Therapeutics

Environmental Strategy

1 Overview

2 Bio CDMO Business

3 Life Sciences Business

4 Technological Advantages

5 Environmental Strategy

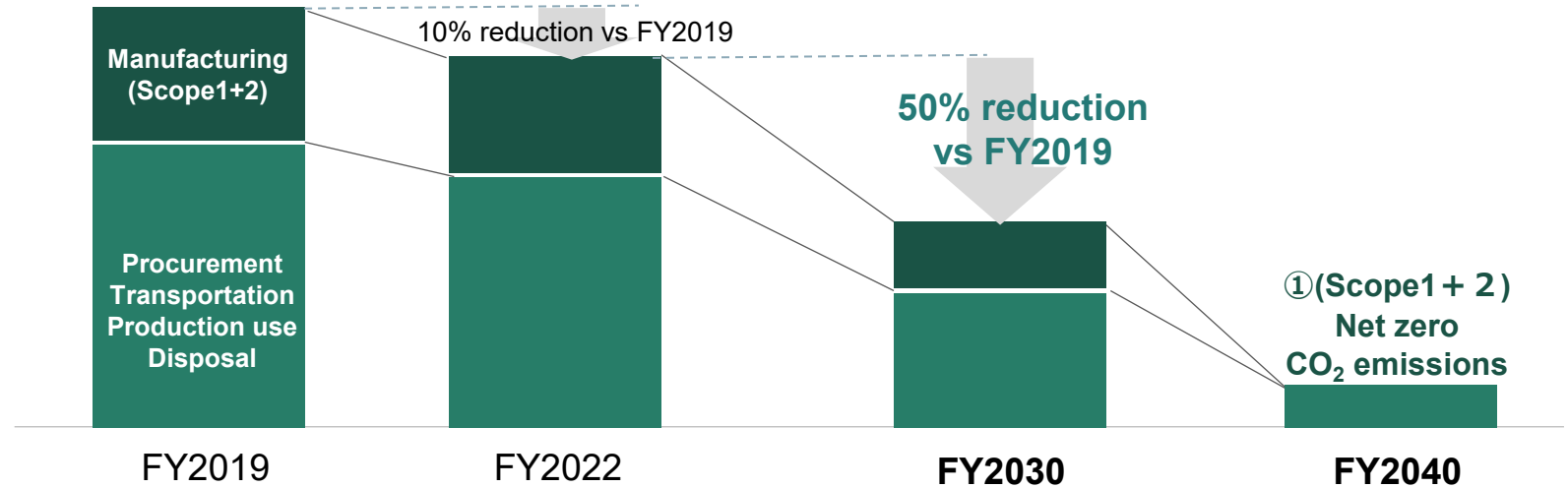
6 Summary

5 | Carbon Neutral Production

At each Bio CDMO and Life Science business site, we are promoting "Green Value Manufacturing," which has low CO₂ emissions, through introduction of renewable energy.

CO₂ emissions reduction targets

- ① **CO₂ emissions from manufacturing (Scope1+2*)**
Achieve net Zero in FY2040
(50% reduction by FY2030, compared to FY2019)
- ② **Reduce CO₂ emissions across entire product life cycle**
50% reduction by FY2030, compared to FY2019



※1
Scope1: Direct emission of greenhouse gases by business operator
Scope2: Indirect emissions through use of electricity and heat/steam supplied by other companies

Measures to achieve carbon neutral production

Bio CDMO



① Conversion to electricity derived from renewable energy sources and Installing electric boilers



① New facilities at NC sites to use 100% electricity derived from renewable energy sources
② Manufacturing close to customers reduces CO₂ emissions required for transportation, etc.

Life science



① **Installing electric boilers to achieve 100% renewable energy by 2024**



*All Fujifilm Group sites in North American will introduce virtual PPA (Power Purchase Agreements), and all electricity used will be converted to renewable energy in 2026 or later.

Summary

1**Overview****2****Bio CDMO Business****3****Life Sciences Business****4****Technological Advantages****5****Environmental Strategy****6****Summary**

6 | Growth Strategy

To support our partners (pharmaceutical companies, biotech, and academia) in delivering innovative drugs to many patients, we provide drug discovery support as well as brisk and plentiful production and supply through End-to-End solutions

1

Developing high-capacity production and supply

- Active capacity expansion: large and small/medium tanks, fully integrated production from API to formulation/packaging
- Supply of culture medium at global bases

2

Investing in new modalities to treat unmet diseases

- Cellular therapeutics: Increased production capacity, expansion of iPSC lines and licensing
- ADC: Providing End-to-End services

3

Leveraging technological capabilities

- Developing future game changer "continuous production platform technology" ahead of competitors
- Development and productivity improvement of new modalities such as gene/cell therapeutics

4

Achieving carbon neutral production

- Introduction of renewable energy and reduction of CO2 emissions during transportation

FUJIFILM
Value from Innovation