

IR DAY 2024

Life Science

AGC Inc.

June 4, 2024





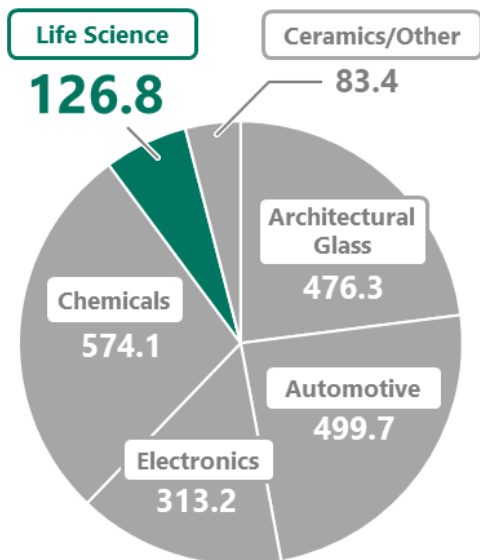
1. Overview of Life Science Business	—————	P.3
2. Current Situation and Future Outlook	—————	P.7
3. Business Strategy and Performance Targets	—————	P.9
4. Appendix	—————	P.16

1. Overview of Life Science Business

FY2023 Sales (Billion Yen)

AGC Group

2019.3 billion yen



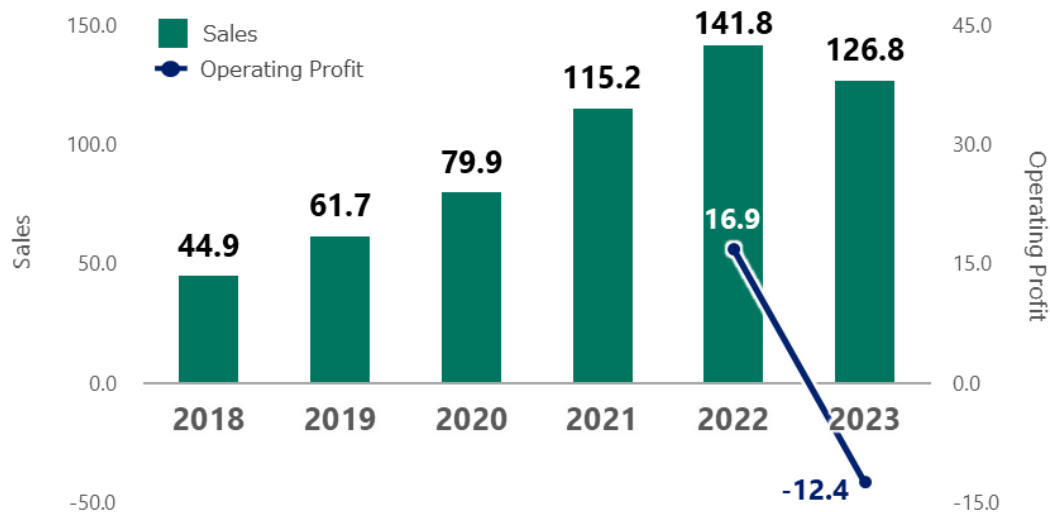
Main Life Science businesses

Business domain		Service overview
Small molecule pharmaceuticals and agrochemicals CDMO	Small molecule pharmaceuticals CDMO	Contract development and manufacturing of small molecule pharmaceuticals
	Agrochemicals CDMO	Contract development and manufacturing of agrochemicals
Biopharmaceuticals CDMO		Contract development and manufacturing of biopharmaceuticals (microbial, mammalian cell culture, gene and cell therapy, pDNA, mRNA, exosomes)

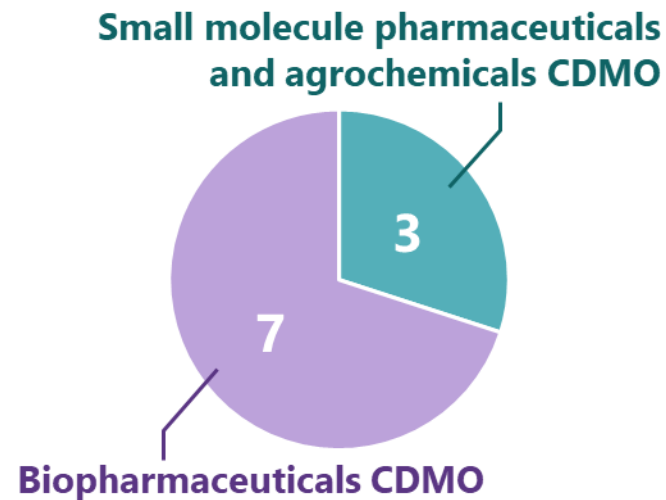
Financial Performance

- In 2023, sales and profits declined due to the delay in the launch of new US lines and the deterioration in the market environment, but the scale of the business increased steadily thanks to intensive investment.

Sales and Operating Profit (Billion Yen)



FY2023 Sales Breakdown



*Sub-segment information within the Chemicals segment is disclosed before 2021 (sales only), and on a stand-alone segment basis after 2022 (2022 figures are for reference only).

History of Life Science Business

- In 1973, the Life Science Team was launched as a research unit, and commercial operations began in the 80s.

1973 Launched The Life Science Team to investigate the applicability of AGC's fluorination technology to pharmaceutical & agrochemical production

Small molecule pharmaceuticals/agrochemicals	Biopharmaceuticals
1985 Started contract manufacture/supply of fluorinated intermediates for use in antibiotics	1984 Formed the Biochemical Group focused on biopharmaceutical development
1997 Established AGC Wakasa Fine Chemicals (currently AGC Wakasa Chemicals)	2000 Formally launched the protein contract manufacturing business
2003 Established a GMP-compliant manufacturing facility for clinical stage drug substances & intermediates at Chiba Plant	2008 Established a new facility at Chiba Plant with 10-fold higher capacity
2008 Obtained marketing approval for tafluprost, an anti-glaucoma drug substance	2016 Acquired biopharmaceuticals CDMO in German (currently Heidelberg site)
2013 Established a new plant, Kaminaka Plant, in the Wakasa Techno-Valley (AGC Wakasa Chemicals)	2017 Acquired biopharmaceuticals CDMO with sites in Europe and US (currently Seattle & Copenhagen sites)
2019 Acquired drug substance manufacturing plant in Spain (currently AGC Pharma Chemicals Europe)	2020 Established new mammalian cell culture facility at Chiba Plant
2019 Increased GMP compliant production capacity 10-fold at Chiba Plant	2020 Acquired biopharmaceutical drug substance manufacturing plant in US (currently Boulder site)
2020 Decided to expand facilities at AGC Pharma Chemicals Europe	2020 Acquired gene/cell therapy CDMO in Italia (currently Milan site)
2021 Decided to expand facilities at Kaminaka Plant of AGC Wakasa Chemicals	2021 Acquired U.S. gene therapy manufacturing plant (currently Longmont site)
2022 Decided to expand facilities at AGC Pharma Chemicals Europe	2023 Started mRNA CDMO service (Heidelberg site)

2. Current Situation and Outlook

Current Situation and Outlook of Biopharmaceuticals CDMO

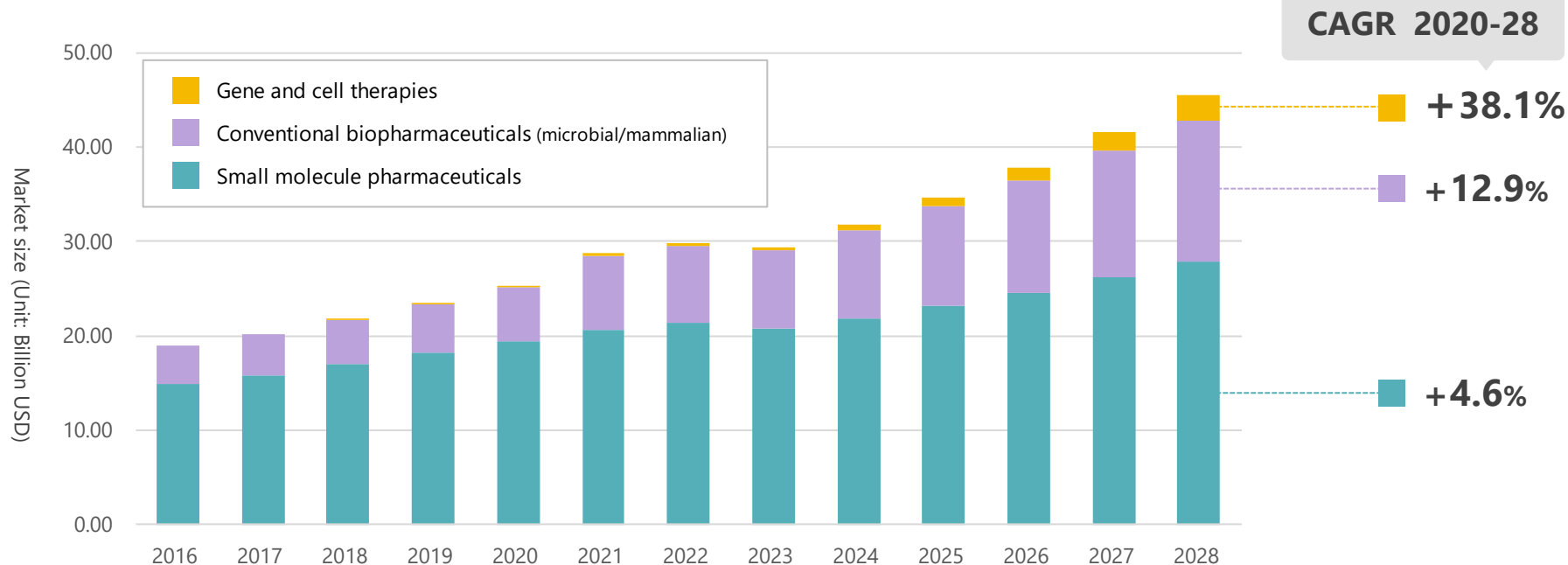
- The impact of the reduced capital inflows into biotech ventures continues. Although the business environment is recovering, **its recovery pace requires close monitoring. The situation going forward will be assessed and necessary measures will be taken.**
- New lines in the U.S. has **resumed commercial operations and is expected to contribute to improvement in earnings from 2024.**

Business environment		
Issues	Temporary leveling off due to repercussions of Covid-related special demand and reduced capital inflows into biotech ventures	Launch of new lines in the U.S.
Current Situation*	Continue to be affected by reduced capital inflows into biotech ventures, but recovery signs are seen. Implemented a rationalization to improve business performance	Delay in launching new lines at Boulder site in the U.S. Drastic measures implemented and resumed commercial operations in end of 2023
Outlook	Business environment is recovering, but the recovery pace will be closely monitored to consider and take additional measures according to market situation	Slowly contributes to improvement in earnings from 2024

3. Business Strategy and Performance Targets

- With the trend towards increased outsourcing, the CDMO market is expanding steadily.

Drug Substance CDMO Market





Vision

To contribute to bettering the world, by providing high-quality life-science related services & products, that require high-level expertise & competence



Strengths

- 1. Providing a high standard of services integrated from 10 sites in three regions of Japan, the US, and Europe**
- 2. Flexible production system providing services from early-stage development to commercial phase**
- 3. Extensive Manufacturing and Inspection Track Record**

Strengths | Flexible to production needs from early-stage development to commercial scale

- Addresses a wide range of production scale needs that vary in accordance with the progress of the development phase of the drug product

Small molecule pharmaceuticals

We have both pilot facilities suitable for small-volume production in the early stages of development and large reactors for commercial phase.

Biopharmaceuticals

AGC is a pioneer in the introduction of **SUBs**, which enable flexible production of small- to medium-scale production, and has the industry's top-class production capacity*. **Large-scale SUS** was introduced in 2020 to accommodate large-scale commercial production.

Bioreactors used for biopharmaceutical production

The main bioreactors used for biopharmaceutical production are "**SUB**" and "**Large-scale SUS**."

SUB (Single-use bag)

A bioreactor that uses single-use bags, which are disposable containers. Since no washing of the bioreactor is required, it is highly efficient and suitable for small- to medium-scale multi-product production.



Large-scale SUS

Large stainless steel bioreactors suitable for large scale commercial production



Scale of production

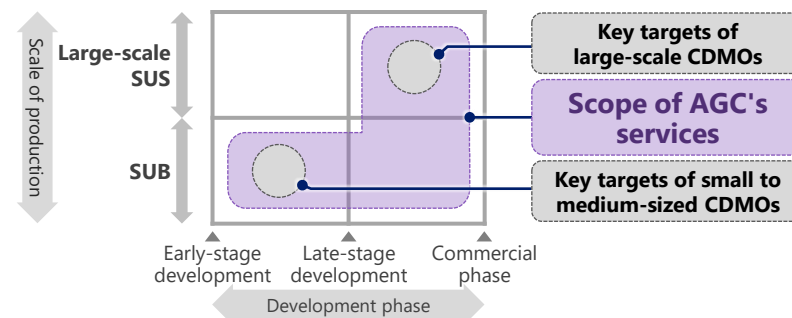
2,000L

12,000L

20,000L

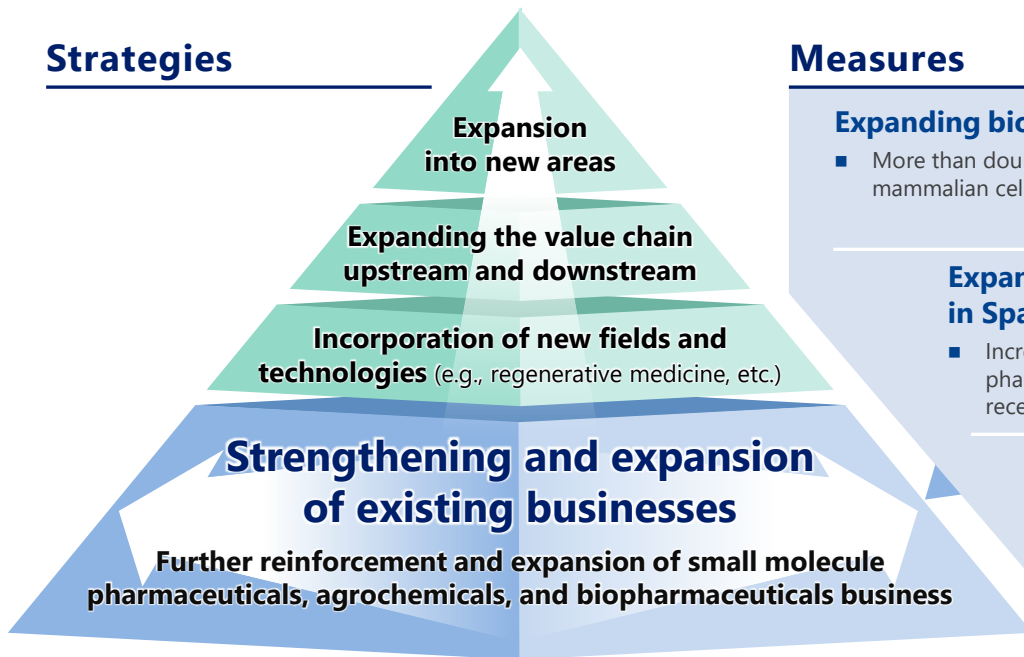
Scope of AGC's services in the biopharmaceutical CDMO business

Combination of SUB and large SUS to meet a **wide range of production scale and development phase**.



- **Further strengthen and expand the core CDMO business for small molecule pharmaceuticals, agrochemicals, and biopharmaceuticals** and consider expansion of services and business areas at an appropriate timing

Strategies



Measures

Expanding biopharmaceuticals CDMO capabilities in Denmark

- More than doubling the manufacturing capacity of the site with the addition of SUB mammalian cell culture bioreactors* Targeted to start operation in 2024.

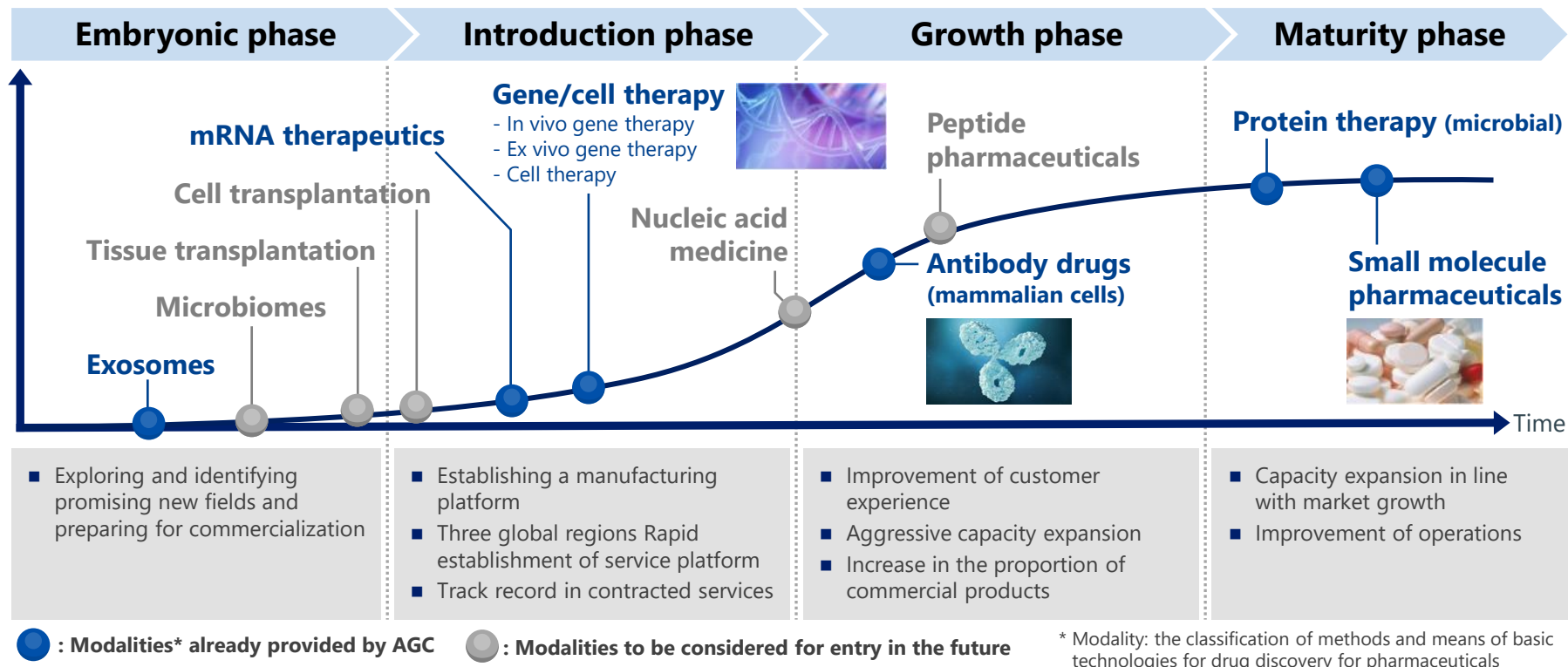
Expanding small molecule pharmaceuticals CDMO capabilities in Spain

- Increasing manufacturing capacity by 30%. Facilities for highly potent active pharmaceutical ingredients (HPAPI), for which demand has been increasing in recent years, will also be added. Targeted to start operation in 2025.

Expanding biopharmaceuticals CDMO capabilities in Japan

- In addition to mammalian cell culture bioreactors which have one of the largest capacity as a CDMO in Japan, the expansion will also include facilities for leading-edge field of mRNA pharmaceuticals and gene and cell therapies. Services are targeted to start gradually in 2025.

Business strategy based on the market maturity of each modality

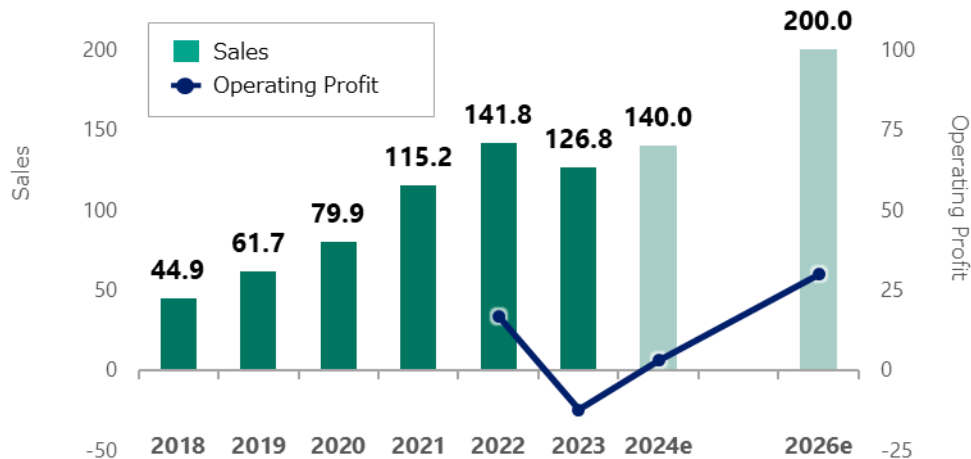


Reference: Arthur D Little, December 23, 2020, Pharmaceutical Development Council document, "Survey on Issues and Initiatives Necessary to Resolve Issues Toward the Industrialization of Pharmaceutical-Related Industries."

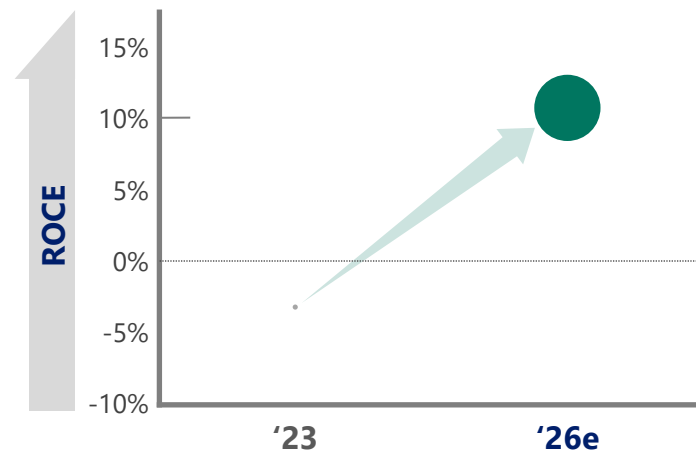
Life Science Segment Performance Targets

- We aim to achieve operating profit of over 30 billion yen and ROCE of over 10% by 2026.
- Continue to consider and take measures to improve business performance based on the current extremely severe business environment.

Image of business performance (Billion Yen)



Change in ROCE and EBITDA**



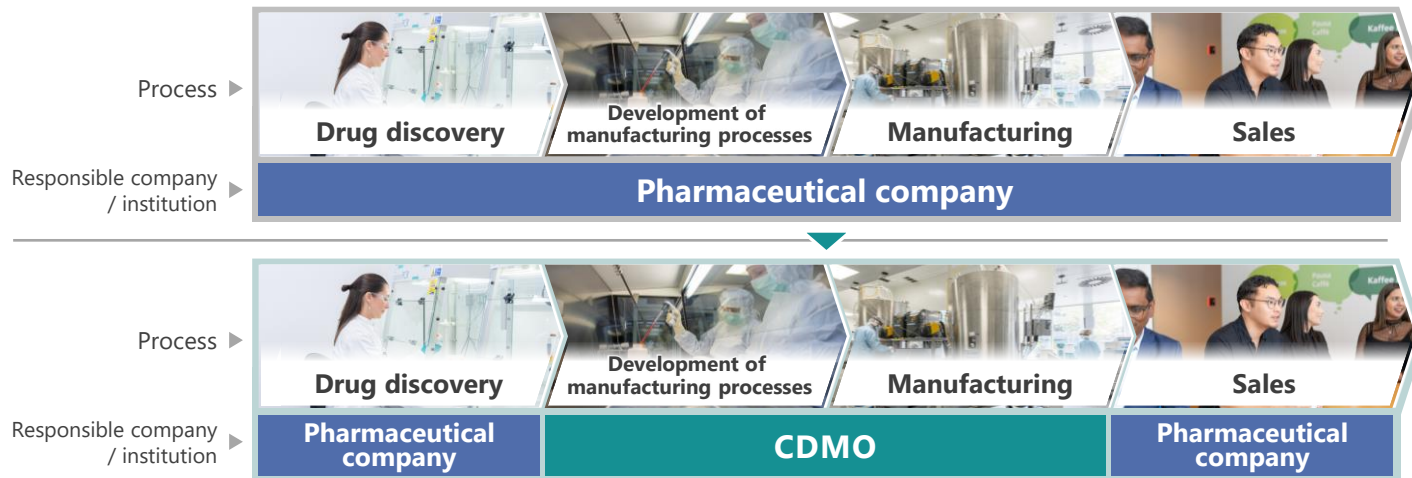
* Sub-segment information within the Chemicals segment is disclosed before 2021 (sales only), and on a stand-alone segment basis after 2022 (2022 figures are for reference only).

**Diameter of each circle : the size of EBITDA

4. Appendix

What is CDMO?

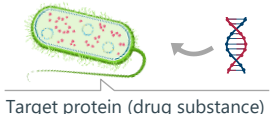
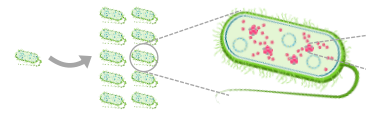
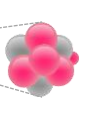

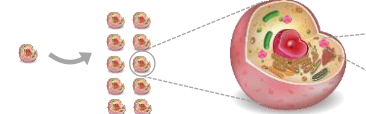
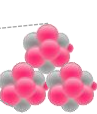
- CDMO: Contract Development & Manufacturing Organization. A company which is a partner to pharmaceutical companies **contracted to provide pharmaceutical manufacturing services and to develop manufacturing processes**.
- As the **structure and manufacturing technology of pharmaceuticals become more complex**, and **huge investments** are required in R&D for new drugs, pharmaceutical companies are increasingly focusing on research to create new drugs and their marketing and **outsourcing the manufacturing and development of the manufacturing process to CDMOs**.



Roles are shared to supply new drugs to the market quickly and stably

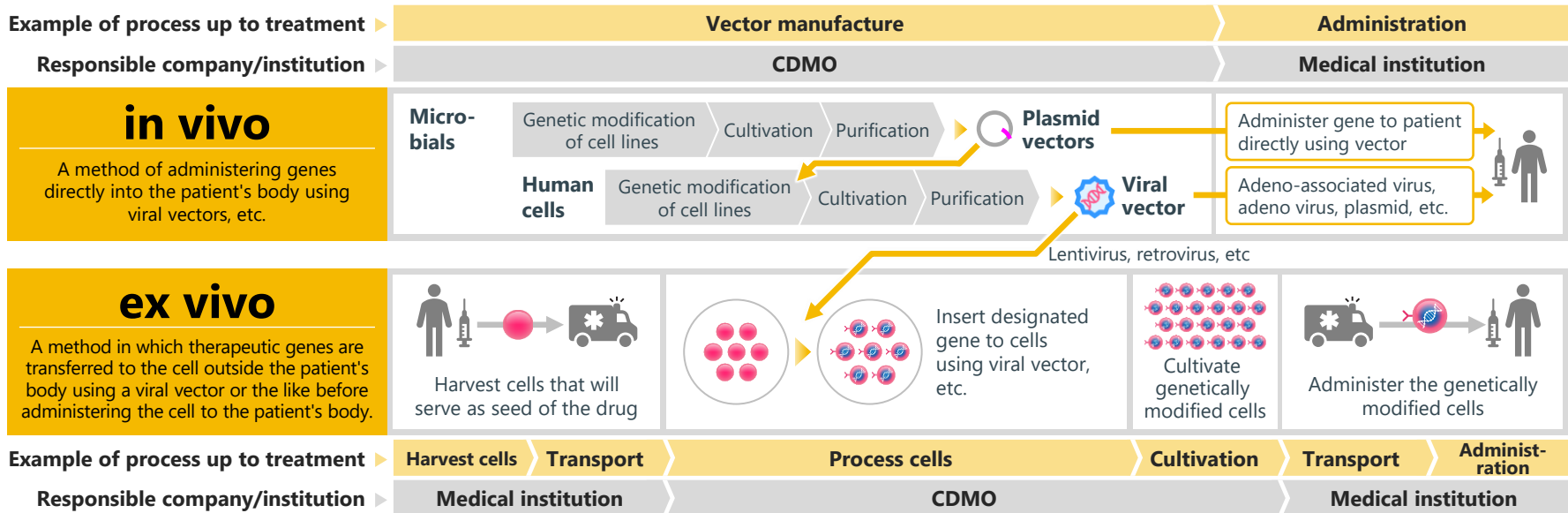
Conventional Biopharmaceuticals CDMO

- AGC receives the “target gene” from the pharmaceutical company, and “cultures” the cell with the target gene, “harvests” and “purifies” to obtain the target protein, on a contract basis
- The manufacturing is for the “target protein (=biopharmaceutical)”. The general flow of the manufacturing process is the same in both microbial and mammalian cells.

Manufacturing process	Introduction of recombinant genes	Culture	Harvest	Purification	Finishing into Product / Marketing
	Introduce a recombinant gene into microbes/mammalian cells.	Increase microbes/mammalian cells carrying the recombinant gene. At the same time, the target protein (=drug substance) also increases.	Collect and purify the target protein (=drug substance)		-
Responsible manufacturer	Pharmaceutical company or CDMO (e.g. AGC)				Pharmaceutical company
Microbial	Introducing recombinant genes into microbes  Target protein (drug substance)	Cultivation of microbes containing recombinant genes 	Separation and purification of target protein (drug substance) 	Molecular weight in the order of 10^4 Structure simple Drug examples insulin (anti-diabetic) GCSF (anti-neutropenic)	-
Mammalian cell	Introduce recombinant gene into mammalian cells  Target protein (drug substance)	Culture of mammalian cells with recombinant gene 	Separation and purification of target protein (drug substance) 	Molecular weight $\geq 10^5$ Structure complicated Drug examples antibodies (e.g. anti-neoplastics, anti-rheumatics), EPO (anti-anemic)	-

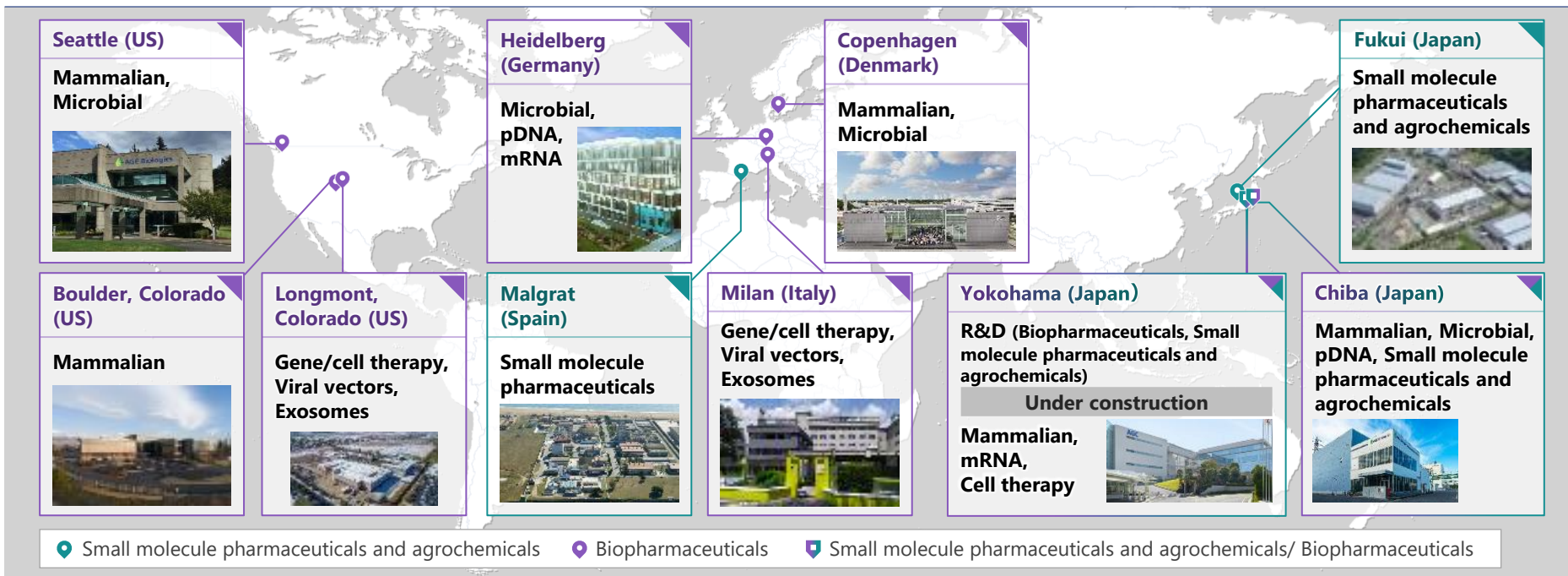
Gene and Cell Therapy CDMO

- In gene/cell therapy CDMO, there are many common basic technologies with conventional biopharmaceuticals CDMO where existing know-how is valuable.
- AGC has strengths in the manufacturing of viral vectors, cell processing technologies, handling of human-derived cells, and manufacturing/QC/QA.

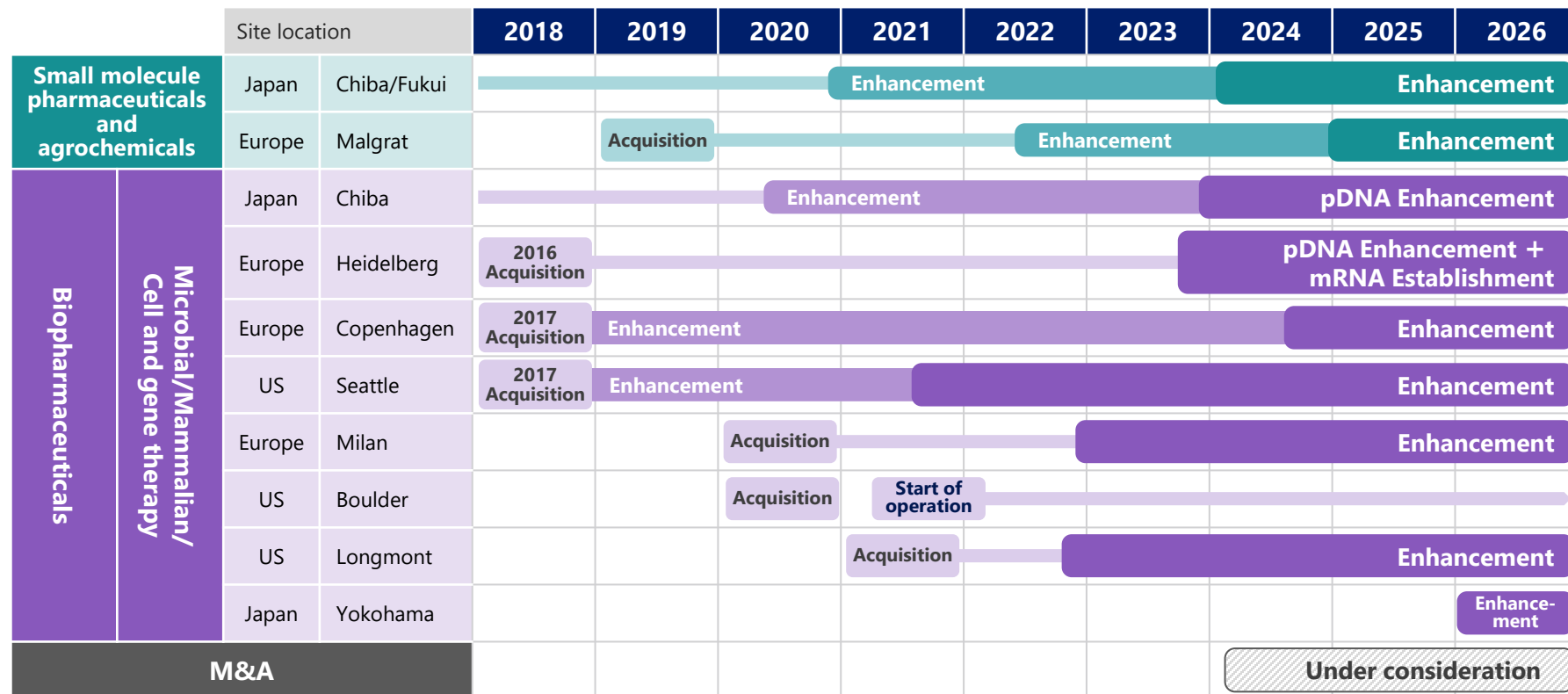


Strengths | Global Service Deployment (1)

- We have established a highly integrated **cGMP system with 10 sites** in Japan, the U.S., and Europe, and provide the same **high standard of development and manufacturing services** in a **wide range of fields** from any of these regions.



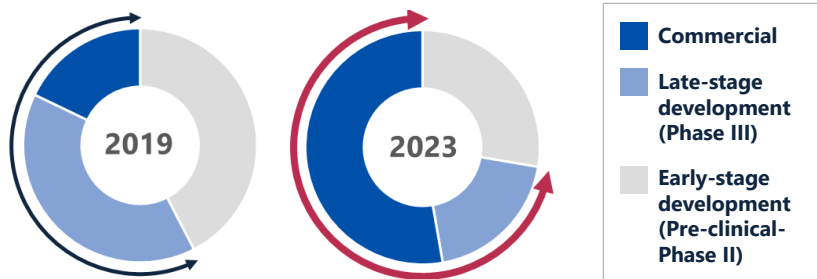
Strengths | Global Service Deployment (2)



Strengths | Extensive Manufacturing and Inspection Track Record (1)

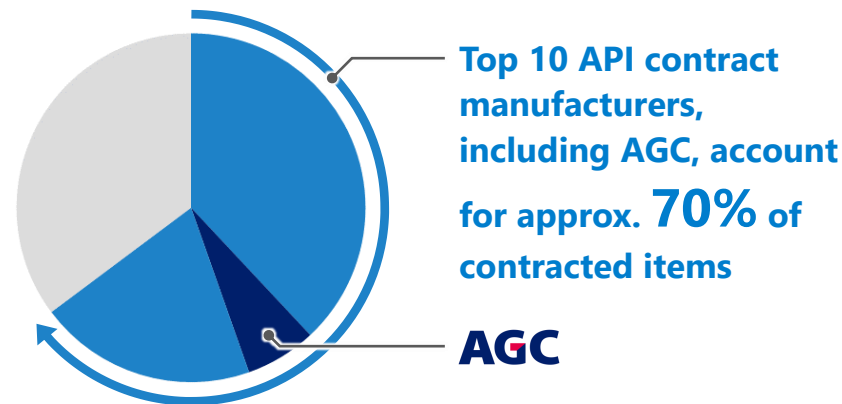
- Based on many years of business experience, we have gained a **wealth of manufacturing and authority inspection track record**, as well as the **trust** of our customers. Increased orders for commercial and late-stage development projects requiring **higher level of cGMP management**. The more track records are accumulated, the more orders are received, leading to a virtuous cycle.

Percentage of biopharmaceutical CDMO contracts (value)



Mid- to long-term growth is expected to continue by the cycle of nurturing the projects together with the client from the early stage of development to the commercial stage where the contract is stable.

Percentage of contracted biopharmaceutical API* (%)



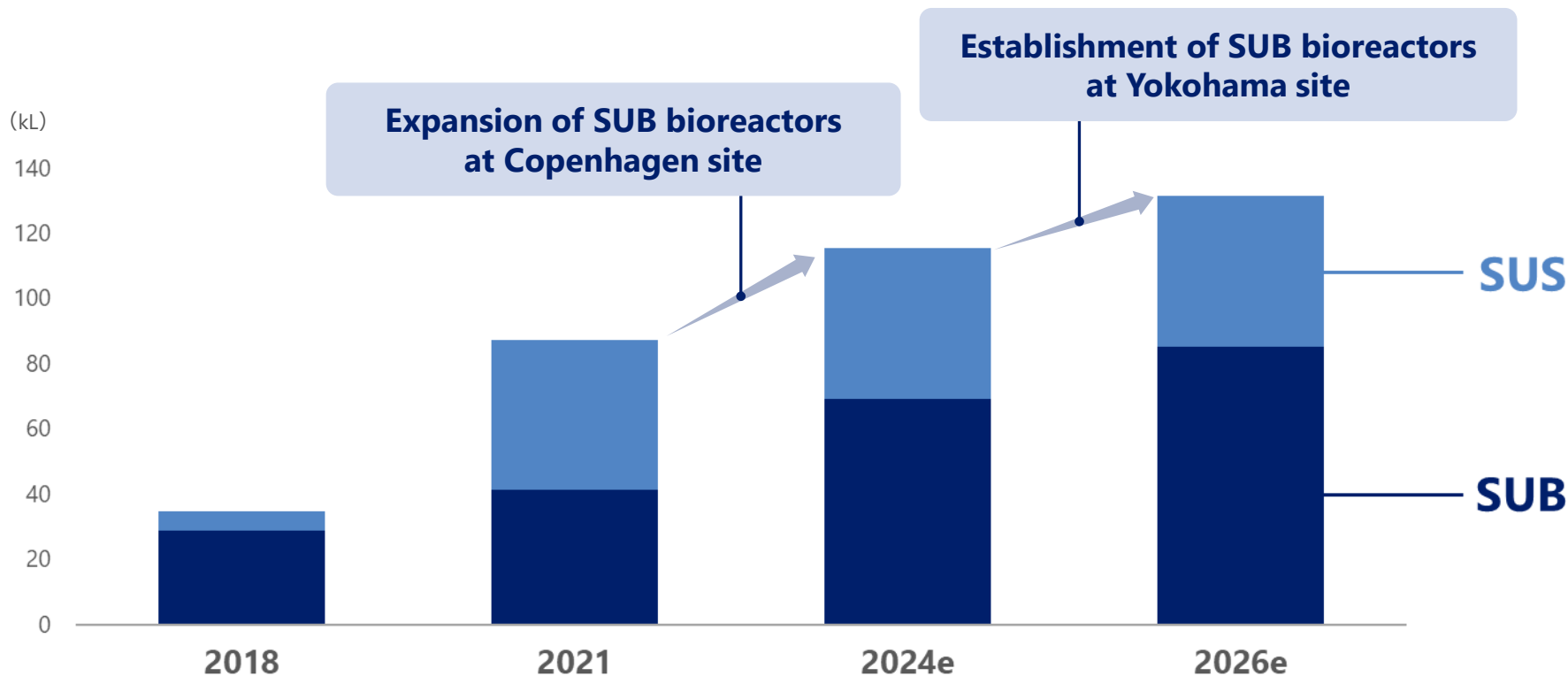
Strengths | Extensive Manufacturing and Inspection Track Record (2)

- With high-level quality and developmental capabilities, we have successfully undergone numerous authority inspections.

Inspection track record

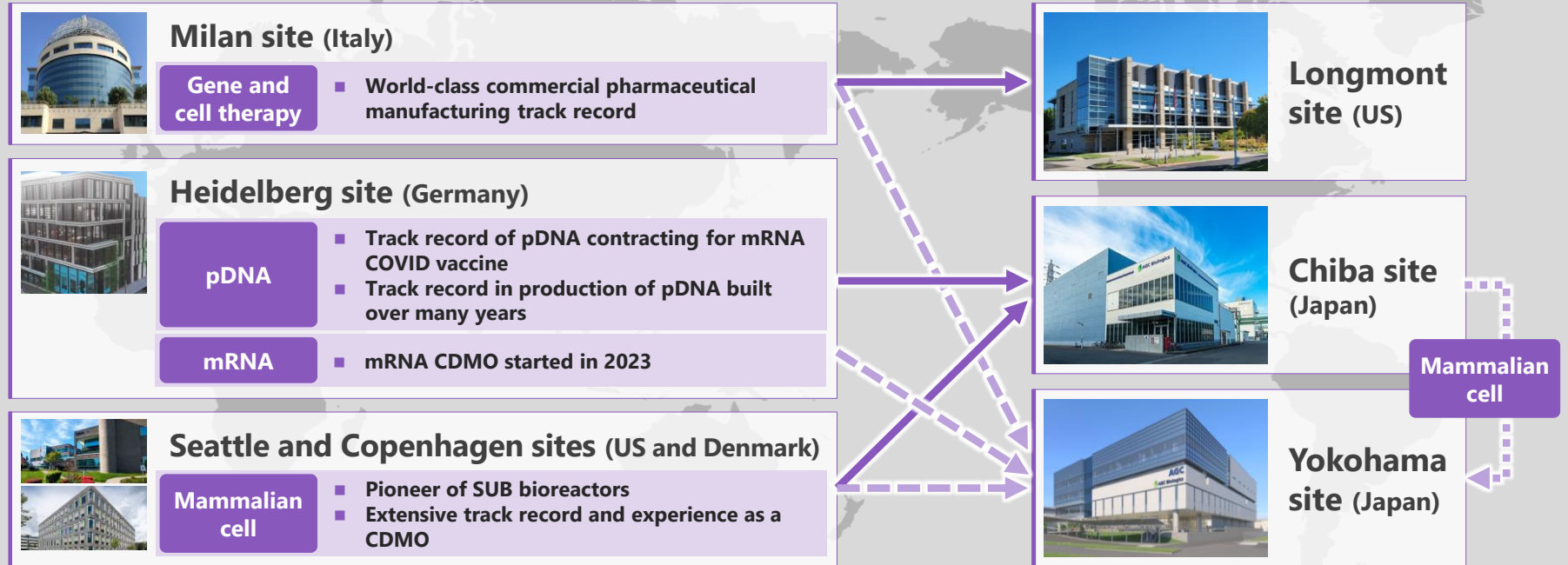
		FDA U.S. Food and Drug Administration	EMA European Medicines Agency	PMDA Pharmaceuticals and Medical Devices Agency
Small Molecules	AGC Chiba Plant	●		●
	AGC Pharma Chemicals Europe Malgrat	●	●	●
Biopharmaceuticals	AGC Biologics Seattle	●	●	●
	AGC Biologics Copenhagen	●	●	●
	AGC Biologics Heidelberg	●	●	●
	AGC Biologics Milan	●	●	
	AGC Chiba Plant			●

Biopharmaceutical CDMO manufacturing capacity (mammalian cells only)

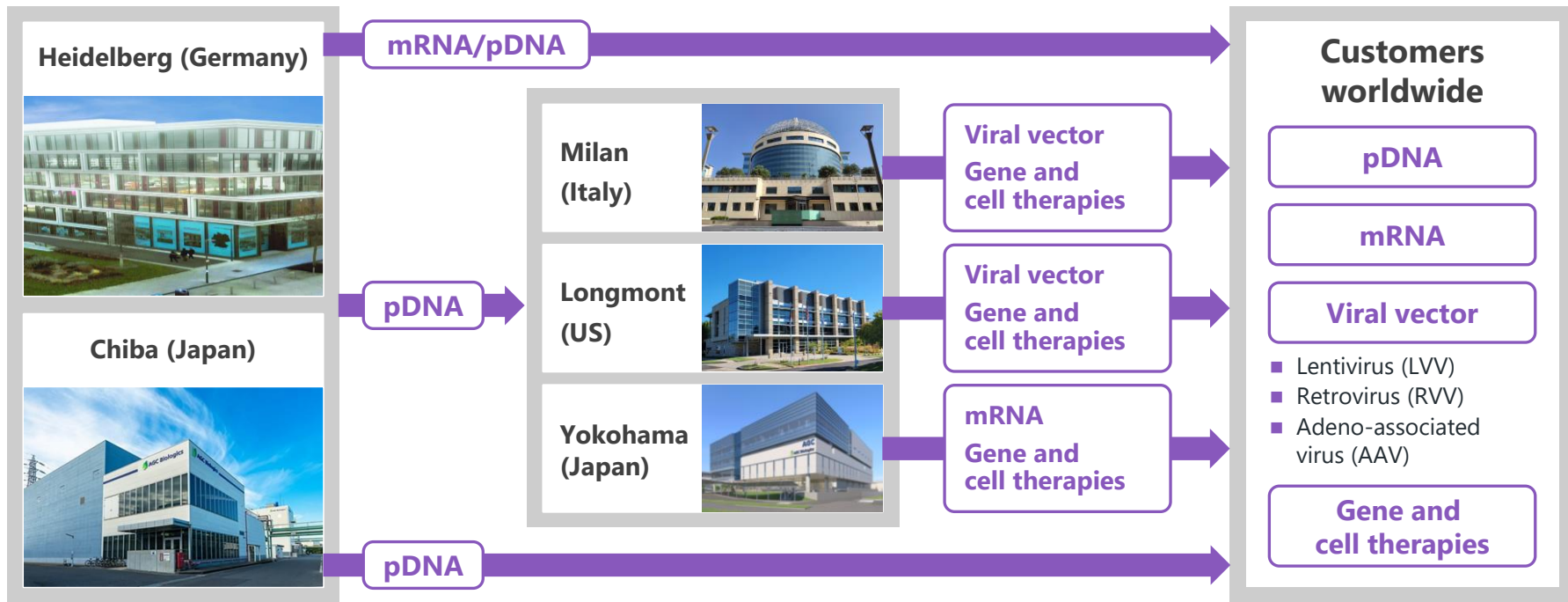


Global Collaboration in Manufacturing and Development Technologies (Technology Transfer)

- We have established a high-quality global service structure by transferring technology from existing sites with cutting-edge technology and extensive track records.

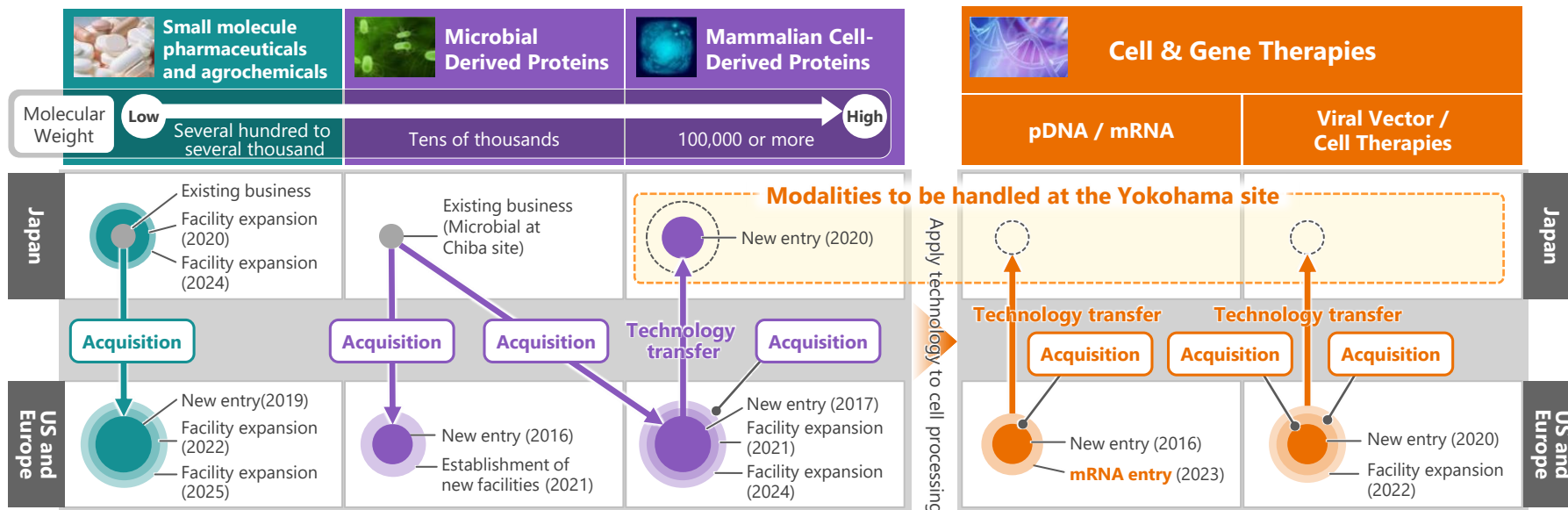


- Integrated services from raw material pDNA to mRNA pharmaceuticals and gene and cell therapies



Expansion of manufacturing and development technologies

- Since acquiring BIOMEVA in 2016, AGC has expanded its business regionally and technologically through substantial capital expenditures and M&As, forming a solid foundation as a pharmaceutical CDMO.
- Now, building on this foundation, further expanding in the cell & gene therapy area.



Improvement of development and manufacturing capabilities for biopharmaceuticals and vaccines (Japan)

- We will introduce dual-use facilities capable of producing cutting-edge biopharmaceuticals such as mRNA therapeutics and switching to vaccine production in the event of a pandemic (service to begin gradually in 2025)
- Contributing to biopharmaceutical ecosystem in Japan

Completed image
(at AGC Yokohama Technical Center)



One of the largest* CDMO facilities in Japan



**Cutting edge and
multiple modalities**



**Extensive knowledge
cultivated in Japan,
the United States,
and Europe**

Contribution to Sustainability Issues

- We are promoting **sustainable business activities** such as environmental impact and supply chain management with consideration for human rights. These are also criteria for supplier selection by pharmaceutical and agrochemical companies.
- We have received **strong supplier ratings for sustainability** from the international rating agency **Ecovadis**.

PLATINUM (only the top 1% are certified)



GOLD (only the top 5% are certified)



Examples of Social value provided by the life science business

- We will contribute to the improvement of "Well-being" through medical and agrochemical CDMO services, while entering and developing technologies in cutting-edge fields.

Well-being

Small molecule pharmaceuticals and agrochemicals CDMO



Small molecule pharmaceuticals CDMO

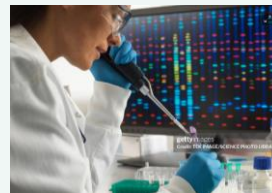


Agrochemicals CDMO

Biopharmaceuticals CDMO



Conventional Biopharmaceuticals CDMO



Gene and cell therapy CDMO

Next-generation areas

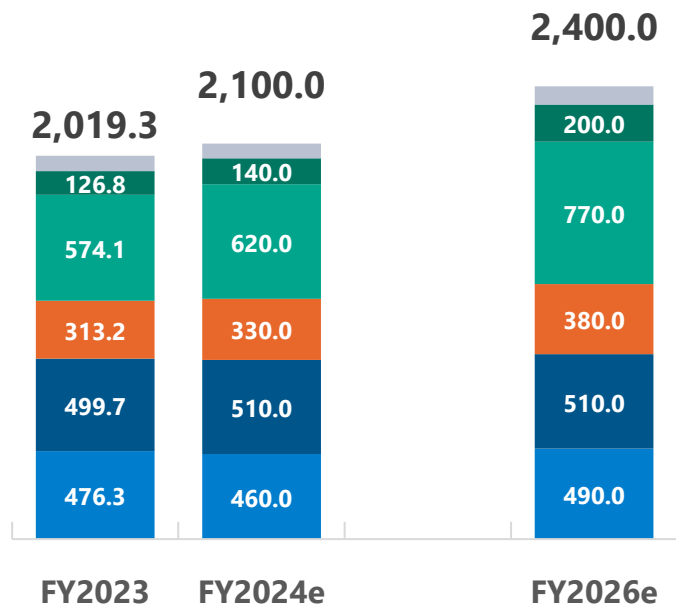


Next-generation bio

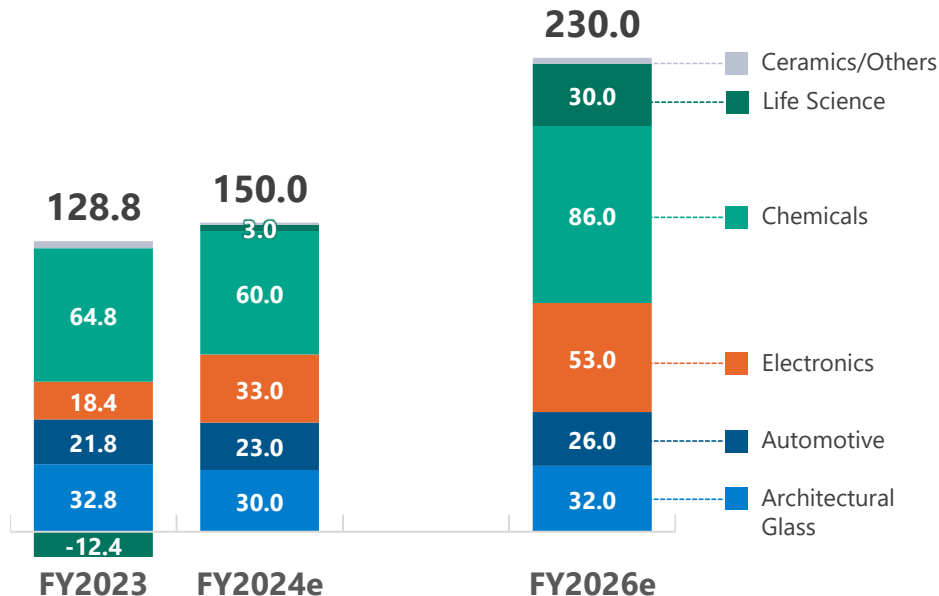
Next-generation areas

Image of Performance by Segment

Net sales (Billion yen)

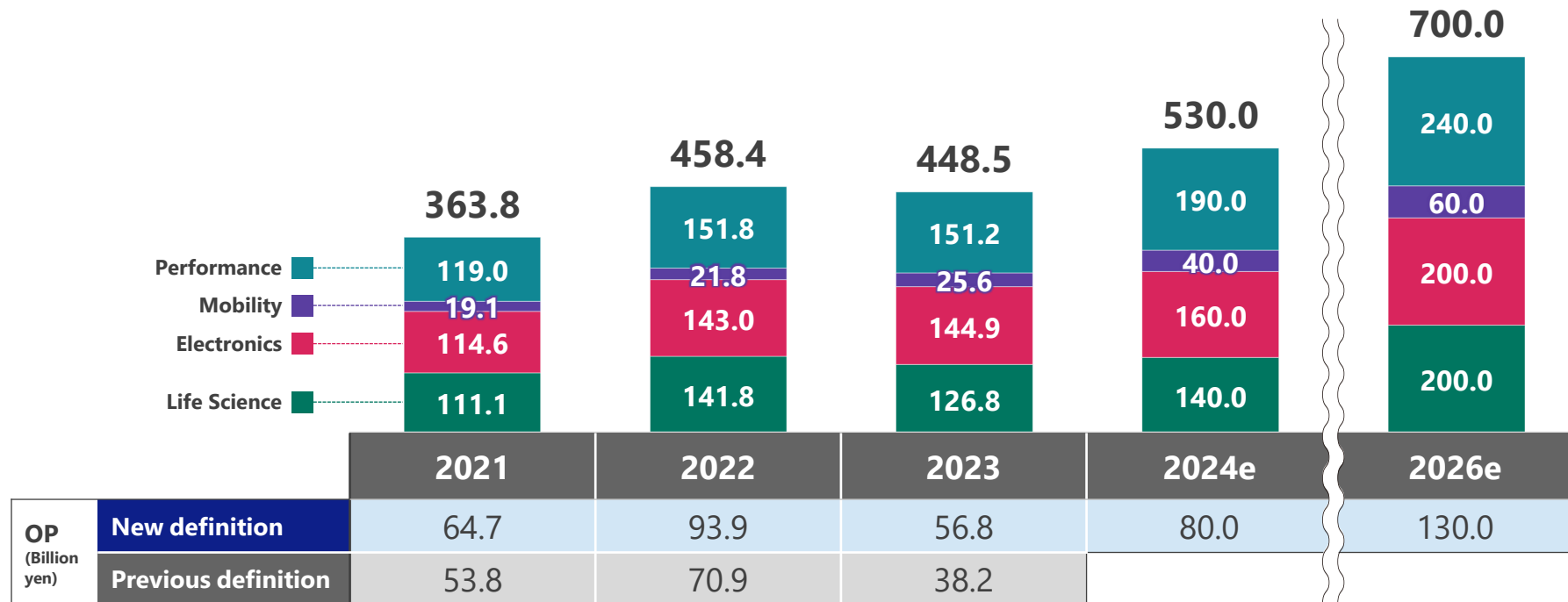


OP (Billion yen)



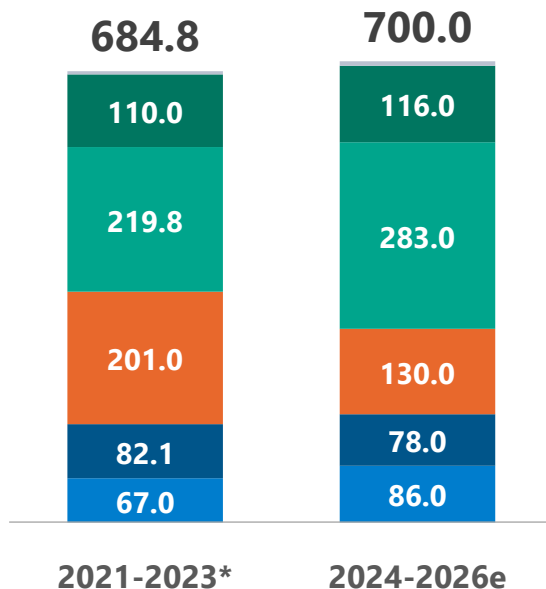
Strategic Business Performance Image

Strategic business net sales (Billion yen)

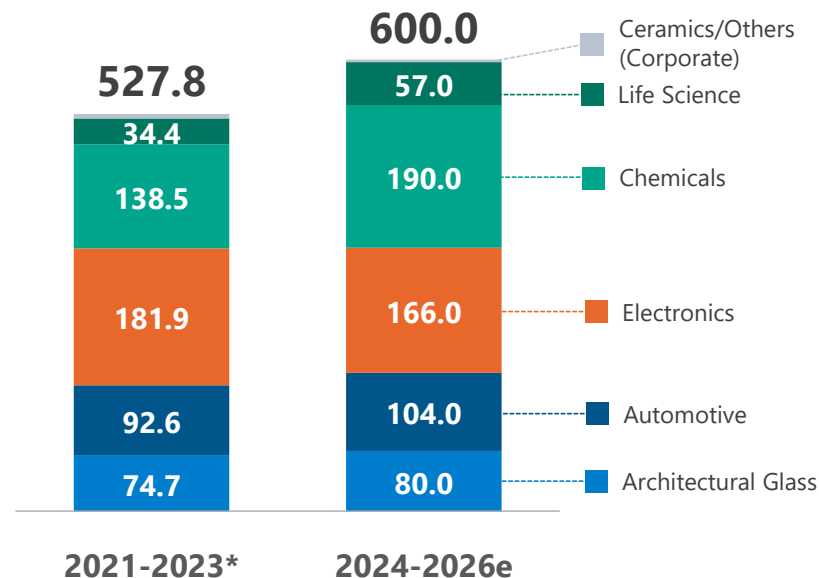


AGC plus-2026 CAPEX and Depreciation & Amortization

CAPEX (Billion yen)



Depreciation & amortization (Billion yen)

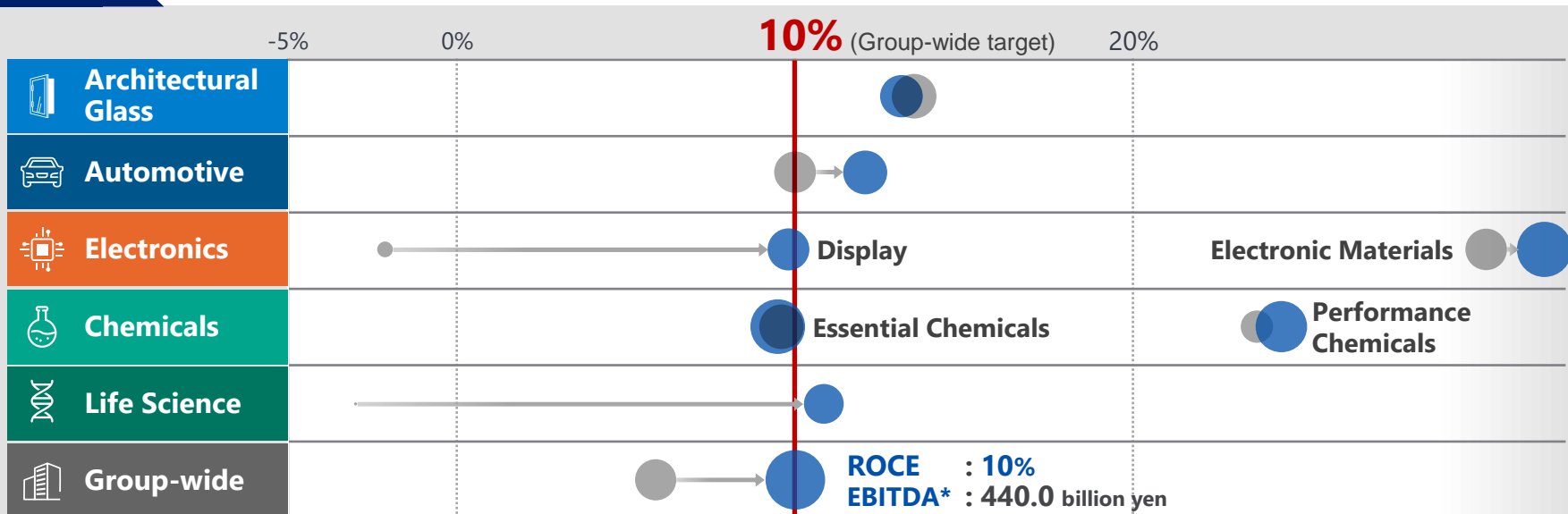


ROCE of Each Business

- We will continue to aim for a Group-wide ROCE of **10% or higher**

ROCE

● 2023 Actual vs ● FY2026 Projection



ROCE : (OP forecast of the year) ÷ (Operating asset forecast at the year-end),

Group-wide OP by business is after allocation of common expenses; OP for each business is before allocation of common expenses

Diameter of each circle (excluding those of the group-wide section) : the size of EBITDA * **EBITDA** = Operating profit + Depreciation

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Your Dreams, Our Challenge