

# Life Science Business Briefing

The logo for AGC, consisting of the letters 'AGC' in a bold, blue, sans-serif font. A small red square is positioned to the right of the letter 'G'.

**AGC Inc.**  
May 31, 2023

Your Dreams, Our Challenge



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# 1. AGC's Life Science Business Overview



## Overall Strategy

Leveraging the core businesses and the strategic businesses as two wheels, we will shift to an optimal business portfolio and continuously create economic and social value.

### Core Businesses

Establishing long-term, stable sources of earnings by increasing competitiveness of each business



### Strategic Businesses

Create and expand highly profitable businesses that will become future pillars by using AGC's strengths in high-growth fields



# Establishment of Life Science Company

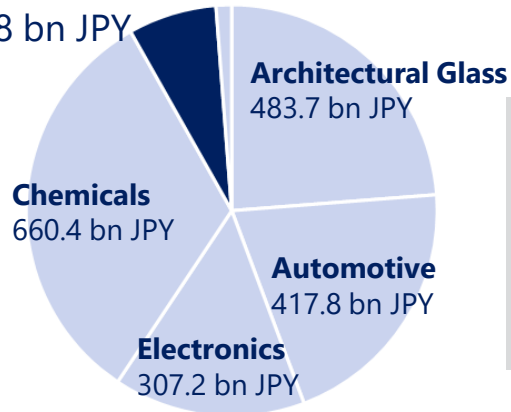
- From 2023, the Life Science Business has been organized as an in-house Company reporting directly to the CEO in order to achieve further business expansion through effective utilization of company-wide management resources and rapid decision making. It has also changed to its own reportable segment.
- Major services\* are **Small molecule pharmaceuticals & agrochemicals CDMO, Biopharmaceutical CDMO**

## Business scale within the AGC Group

(Net sales for the fiscal year ended December 2022)

### Life Science

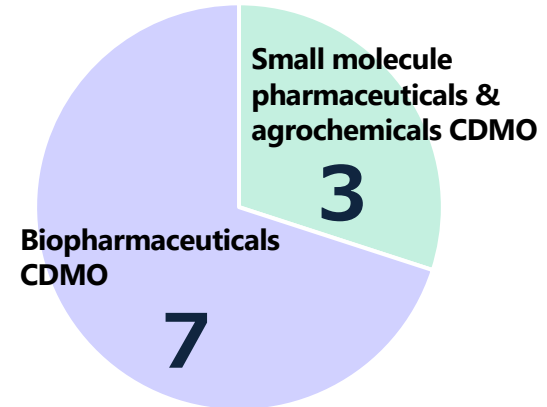
141.8 bn JPY



**No. of employees**  
(As of end-December 2022)  
**Approx. 3,200**

## Breakdown of major services in the Life Science Company

(Net sales for the fiscal year ended December 2022)



\*\*The fine silica business, which was previously included in the Life Science business, has been transferred to the Chemicals business.

# History of AGC's Life Science Business

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

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

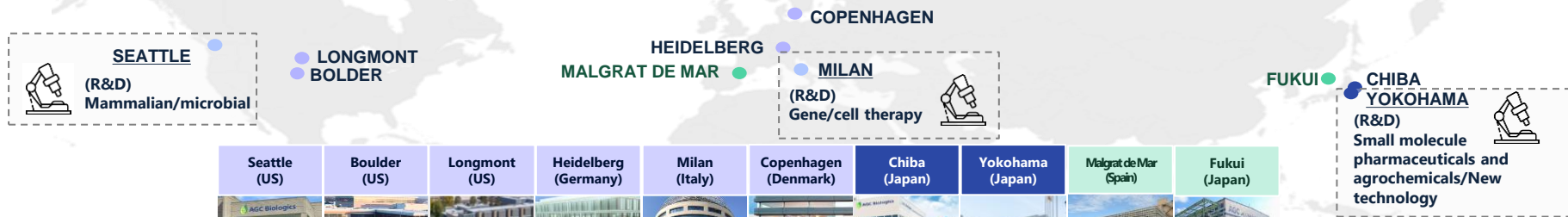
1. Events related to contract development/manufacturing of small molecule pharmaceuticals/agrochemicals	2. Events related to contract development/manufacturing of biopharmaceuticals
<b>1985</b> Started contract manufacture/supply of fluorinated intermediates for use in antibiotics	<b>1984</b> Formed the Biochemical Group focused on biopharmaceutical development
<b>1997</b> Established AGC Wakasa Fine Chemicals. (currently AGC Wakasa Chemicals)	<b>2000</b> Formally launched the protein contract manufacturing business
<b>2003</b> Established a GMP-compliant, multi-purpose facility for manufacturing clinical stage drug substances & intermediates at Chiba Plant	<b>2008</b> Established a new facility at Chiba Plant with 10-fold higher capacity
<b>2008</b> Obtained marketing approval for tafluprost, an anti-glaucoma drug substance	<b>2016 Acquired</b> Biomeva, a major German biopharmaceutical contract manufacturing organization (currently AGC Biologics (Heidelberg))
<b>2013</b> Established a new plant, Kaminaka Plant, in the Wakasa Techno-Valley (AGC Wakasa Chemicals)	<b>2017 Acquired</b> CMC Biologics, with several manufacturing bases in Europe and US (currently AGC Biologics (Seattle & Copenhagen))
<b>2019 Acquired</b> drug substance manufacturing plant in Spain (currently AGC Pharma Chemicals Europe)	<b>2020</b> Established new mammalian cell facility at Chiba Plant
<b>2019</b> Increased production capacity 10-fold at Chiba Plant	<b>2020 Acquired</b> AstraZeneca's U.S. bio-pharma plant (currently AGC Biologics (Boulder))
<b>2020</b> Decided to expand facilities at AGC Pharma Chemicals Europe	<b>2020 Acquired</b> Molmed in the gene/cell therapy area (currently AGC Biologics (Italy))
<b>2021</b> Decided to expand facilities at Kaminaka Plant of AGC Wakasa Chemicals	<b>2021 Acquired</b> U.S. gene therapy manufacturing plant (currently AGC Biologics (Longmont))
<b>2022</b> Decided to expand facilities at AGC Pharma Chemicals Europe	<b>2023</b> Started mRNA CDMO service (AGC Biologics (Heidelberg))

## 2. Our Strengths



# 1. Providing a High Standard of Services Integrated from 10 Sites in Three Regions of Japan, the US, and Europe

- We have established a highly integrated cGMP system with **10 sites in the three regions of Japan, the US, and Europe**. We provide the same **high standard of development and manufacturing services** from any region in a wide range of fields including chemical synthesis, microbial, mammalian cells, pDNA, mRNA, gene and cell therapy, exosomes, and more.
- We will continue to deepen and improve CDMO services by **refining our technological capabilities, including those for new technologies, at each R&D center and deploying them in the three regions.**



	Seattle (US)	Boulder (US)	Longmont (US)	Heidelberg (Germany)	Milan (Italy)	Copenhagen (Denmark)	Chiba (Japan)	Yokohama (Japan)	Malgrat de Mar (Spain)	Fukui (Japan)
Small molecule pharmaceuticals and agrochemicals										
Microbial	●			●		●	●		●	
Mammalian cells	● (SUB)	● (SUS)				● (SUB)	● (SUB)	● (SUB)		
pDNA				●			●			
mRNA				●				●		
Viral vectors			●		●			●		
Cell therapy			●		●			●		
Exosomes			●		●					
R&D	●				●			●		

Under consideration



## 2. Flexible Production System Providing Services from Early – stage development to Commercialization

- Addresses a wide range of production scale needs that change as development progresses**
  - Small molecule pharmaceuticals: We have kilo-lab pilot facilities suitable for small volume production in early-stage development and large-scale reactors for commercial use.
  - Biopharmaceuticals: Ahead of other companies, we introduced **SUBs\***, which are strong in the flexible production from small to medium scale of mammalian cells, the current mainstream. **Currently, our SUB production capacity is the global No. 2\*\*.**  
In 2020, **large-scale SUS\*\*\*** bioreactors were introduced to meet the needs for large commercial products such as blockbuster drugs.
- On the strength of our SUB's abundant capacity and track record, we are building up contracts for early-stage development projects and working with customers to nurture them into late-stage development and commercialization that are expected to generate long-term contract, resulting in continued growth over the medium to long term.**

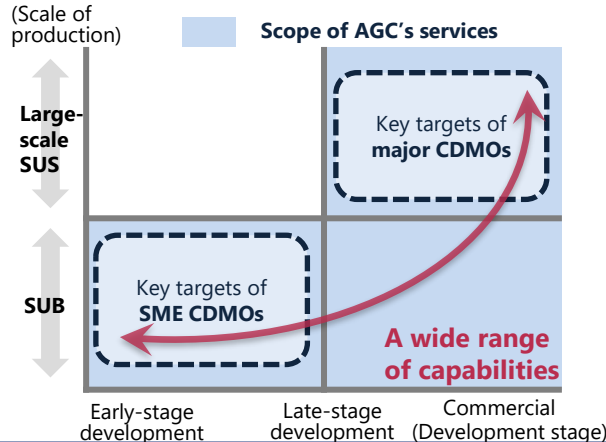
### Scope of AGC's services in the biopharmaceutical business



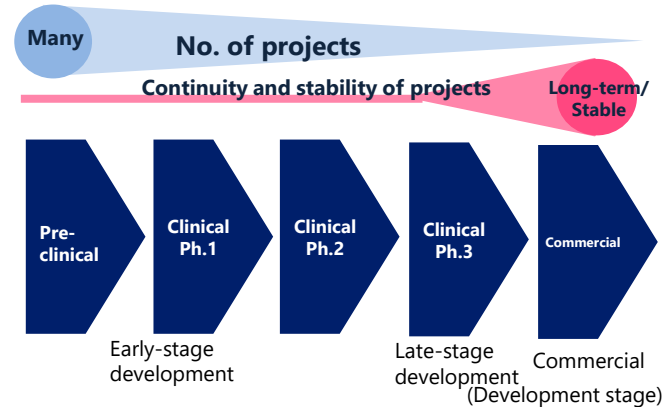
**\*\*\*Large-scale SUS:**  
Large stainless steel bioreactors. Suitable for large scale commercial pharmaceutical production.



**\*SUB:**  
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.



### Changes in the nature of contracted projects as development progresses

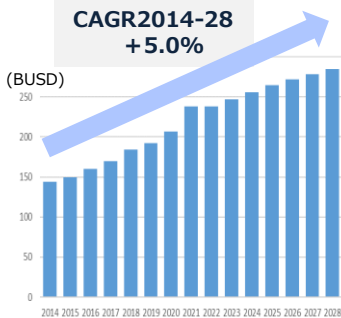


# 3. Extensive Manufacturing and Inspection track record

- Advanced quality and manufacturing control systems and strict inspections by regulators are essential for Commercial and/or Late-stage development projects
- To ensure the early launch of pipelines for which significant development investment has been made, **Customers (pharmaceutical companies) tend to seek outsourcing to trusted and proven CDMOs**
- Through many years of experience as a CDMO, **AGC has gained a wealth of manufacturing and inspection track record, as well as customer trust.** The number of commercial pharmaceutical contracts has increased as a result.

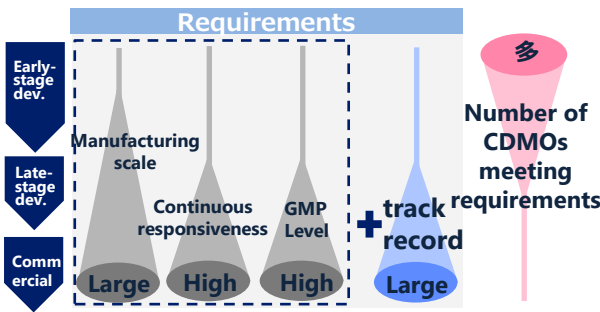
**Creating a virtuous cycle where the more projects we complete, the more projects we obtain.**

## Pharmaceutical R&D Expenses\*



**R&D expenses increase year by year. Return on investment by early and reliable launch of new drugs is essential.**

## Changes in the level of requirements for CDMOs as development progresses



Due to the risk of lost opportunities caused by delayed launch schedules, **"track record" is an important requirement** for CDMO selection, especially for late-stage development and commercial projects, as it is a proof of capability.

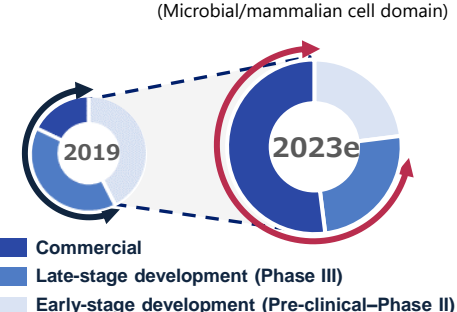
**Limited number of CDMOs with an extensive track record in late-stage development and commercial projects.**

## Comparison of biopharmaceutical API contracts\*\*



**Projects are concentrated in some CDMOs, including AGC. The track record gained from such projects will become a strength, leading to a virtuous cycle that will increase the number of further contracts.**

## Percentage of biopharmaceutical CDMO contracts (value)



**Ratio of commercial projects increased. Continued mid- to long-term growth in commercial products due to the prospect of long-term, continuous contracts.**

\*Source: AGC estimates based on Evaluate 2022 World Preview data.

\*\*Source: AGC estimates based on Globaldata (Mar 2023) data.

## 4. Highly Evaluated for Sustainability Promotion

- 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)



# Leveraging Our Strengths for Further Business Growth

By continuing to meet the expectations of our customers through leveraging our strengths, **we will make our business foundation more stable and solid and achieve even higher growth.**

## Serving customers worldwide

Integrated high-level development and production system with 10 sites in three regions (Japan, the US and Europe).



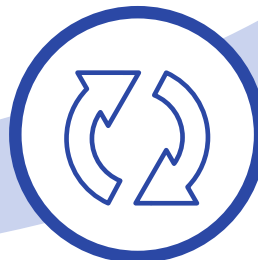
## Flexible production system

Many of the development projects we have undertaken have been commercialized.



## Building up a track record and trust

A virtuous circle where completed orders attract new orders



## Sustainable business activities

Contributing pharmaceutical companies and other customers, patients, and society



# 3. Business Environment



# Current Situation and Outlook (1/2)

## Current

### Disappearance of extraordinary demand related to COVID:

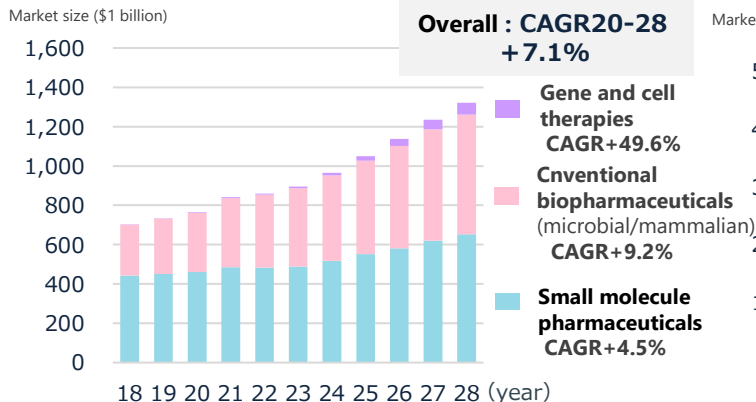
Due to changes in the global pandemic, extraordinary demand related to COVID has run its course. Contracts for COVID-related products declined.

## Future

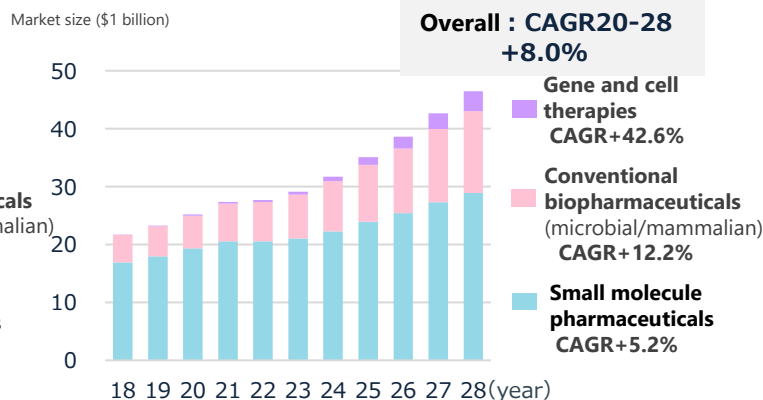
### Acceleration of non-COVID projects:

Both the pharmaceutical and pharmaceutical CDMO markets are expected to expand steadily, even excluding COVID vaccines and therapeutics. Excluding COVID projects, AGC is also seeing steady growth in sales, and we expect sales to increase by at least the same amount in 2023 and beyond.

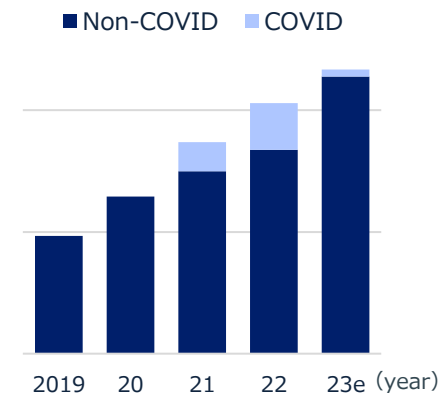
### Prescription Pharmaceutical Market \*(excluding COVID vaccines and therapeutics)



### Drug Substance CDMO Market \*(excluding COVID vaccines and therapeutics)



### AGC's Life Science Revenue

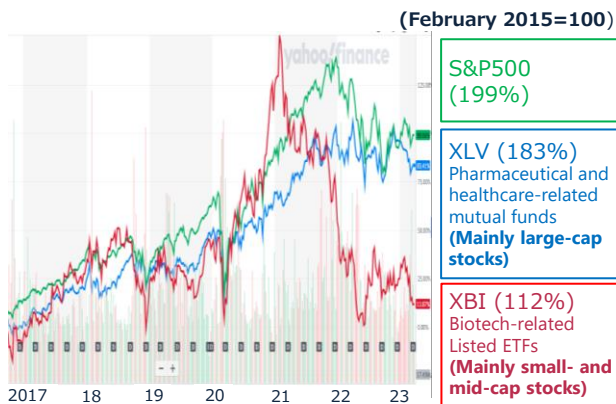


# Current Situation and Outlook (2/2)

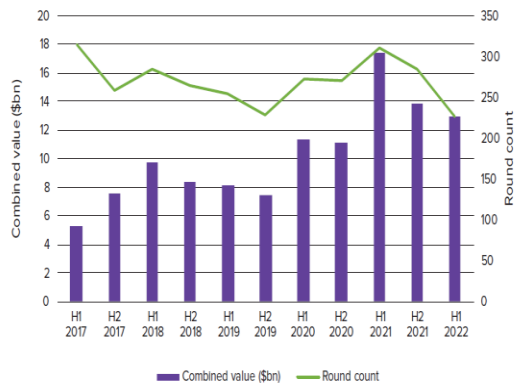
**Current** **Slowdown of early-stage development projects from SME biotechs:**  
Declining special demand for COVID and tightening of global monetary conditions have slowed capital inflows to SME biotechs, mainly for early-stage development projects. AGC's business, which has many transactions with SME biotechs, has been affected to a reasonable degree.

**Future** **Building a business structure that is resilient to the economy and other factors:**  
The recent slump in biotech-related indices looks to have bottomed out and is expected to gradually recover. In addition, the percentage of commercial and late-stage development products, for which long-term contracting is expected, is increasing. We expect stable business growth that is resilient to the economy and other factors.

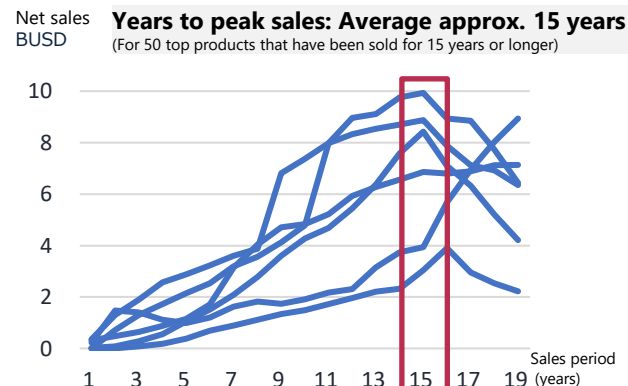
## Stock and mutual fund indices of US-listed companies



## Inflow of funds from VC into biotech\*



## Drug sales period (example of major biopharmaceuticals)\*\*



\*Source : EvaluatePharma® World Preview 2022 Outlook to 2028: Patents and Pricing

\*\*source : Globaldata and AGC estimate

# 4. Our Growth





# Strengthening Existing Businesses: Small molecule Pharmaceuticals & Agrochemicals CDMO Business

Expansion in 2020:  
Approx. 10 times



Chiba (Japan)

Expansion in 2022:  
Approx. 1.3 times



Malgrat (Spain)

Expansion in 2024:  
Approx. 1.5 times



Fukui (Japan)

Expansion in 2024:  
Approx. 1.3 times



Malgrat (Spain)

## Pharmaceuticals



We have invested in expansion of facilities in Japan and Europe, including facilities to handle **pharmaceuticals with highly potent active pharmaceutical ingredients** which are becoming very important in oncology and other diseases, as well as **micronization, kilo-labs, and pilot facilities**.

Providing high value-added CDMO services to meet customer needs.

## Agrochemicals



Meeting growing **need for further safety, including reduction of environmental impact** and focusing on CDMO services for technically challenging projects where process development capabilities are an advantage.

Enhancing our one-stop services from raw material production at the Chiba Plant to active ingredient production at AGC Wakasa Chemicals (Fukui) by investing in expansion at Japan site.

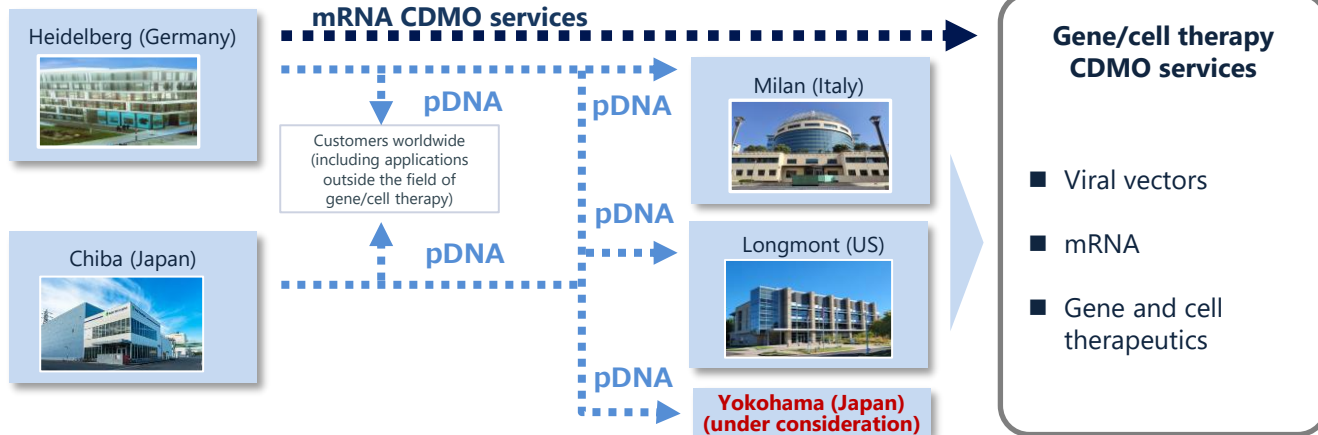
**Providing a wide range of high value-added services globally**, such as reducing environmental impact and responding to pharmaceuticals with high pharmacological activity that require higher safety standards, on the strength of **AGC's diverse and advanced technological capabilities and quality platform**, including fluorine-based synthesis technology cultivated in the chemicals business. Further expansion and M&A are under consideration to meet growing demand.

# Strengthening Existing Businesses: Considering Expanding Biopharmaceutical CDMO Capacity in Japan

- Considering establishing a **new manufacturing facility in Yokohama, as the second domestic biotech site after the Chiba Plant** (target start of operation in 2025), for mammalian biopharmaceuticals, mRNA drugs, and gene therapeutics (viral vectors and cell therapeutics). This will be the second domestic biotech site following the Chiba Plant. Targeted to start operation in 2025.
- One of the largest scale mammalian bioreactors\* for a CDMO in Japan.
- In addition to microorganisms and mammalian cells, **establish a tri-region structure in the field of gene therapeutics in Japan, Europe, and the US**. Development and manufacturing services based on advanced technologies are provided from Japan through the utilization of technology from sites in Europe and the US.

## Initiatives in the field of gene and cell therapy

## Developing a wide range of products from raw material pDNA to gene-cell therapeutics including viral vectors



## Yokohama (under consideration)



# Incorporation of New Fields and Technologies: Launch of Exosome CDMO Services

- We have **launched CDMO services** using human mesenchymal stem cells (hMSCs) and other cell types for exosomal medicines, which are expected to be commercialized in the future (Milan and Longmont sites).
- External technologies, such as those of partner **RoosterBio, Inc.**, are also used flexibly as needed.
- In 2023 **Jikei University School of Medicine commissioned a trial manufacture of an exosome therapeutic** (for idiopathic pulmonary fibrosis).
- As with other advanced technologies, AGC is considering the timing of service expansion while monitoring market trends.

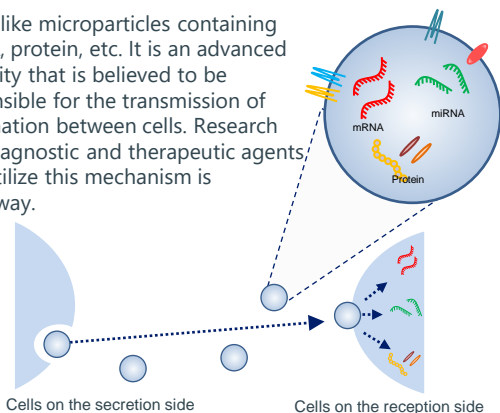


**Jikei University  
School of Medicine**

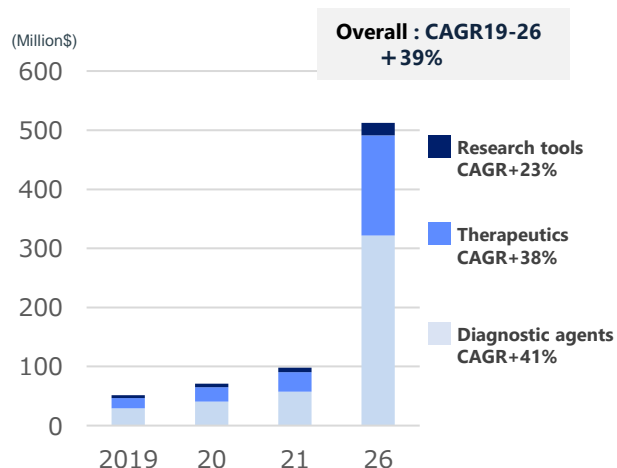
## About exosomes

Extracellular vesicles (EV\*) that are secreted by cells and are about 100nm in diameter.

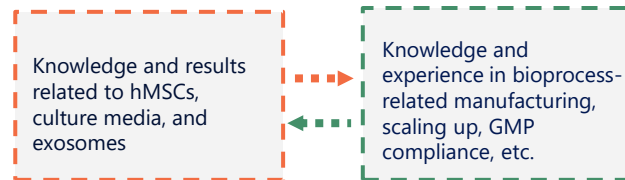
Foam-like microparticles containing mRNA, protein, etc. It is an advanced modality that is believed to be responsible for the transmission of information between cells. Research into diagnostic and therapeutic agents that utilize this mechanism is underway.



## Exosome market size trend\*\*



## Partnership with RoosterBio



\*EV : Although exosomes are strictly EVs derived from endosomes, it is difficult to distinguish exosomes from EVs formed by other pathways, so in recent years it has been recommended to refer to them collectively as EVs. In this document, EVs containing exosomes are described as exosomes because the designation is more prevalent.

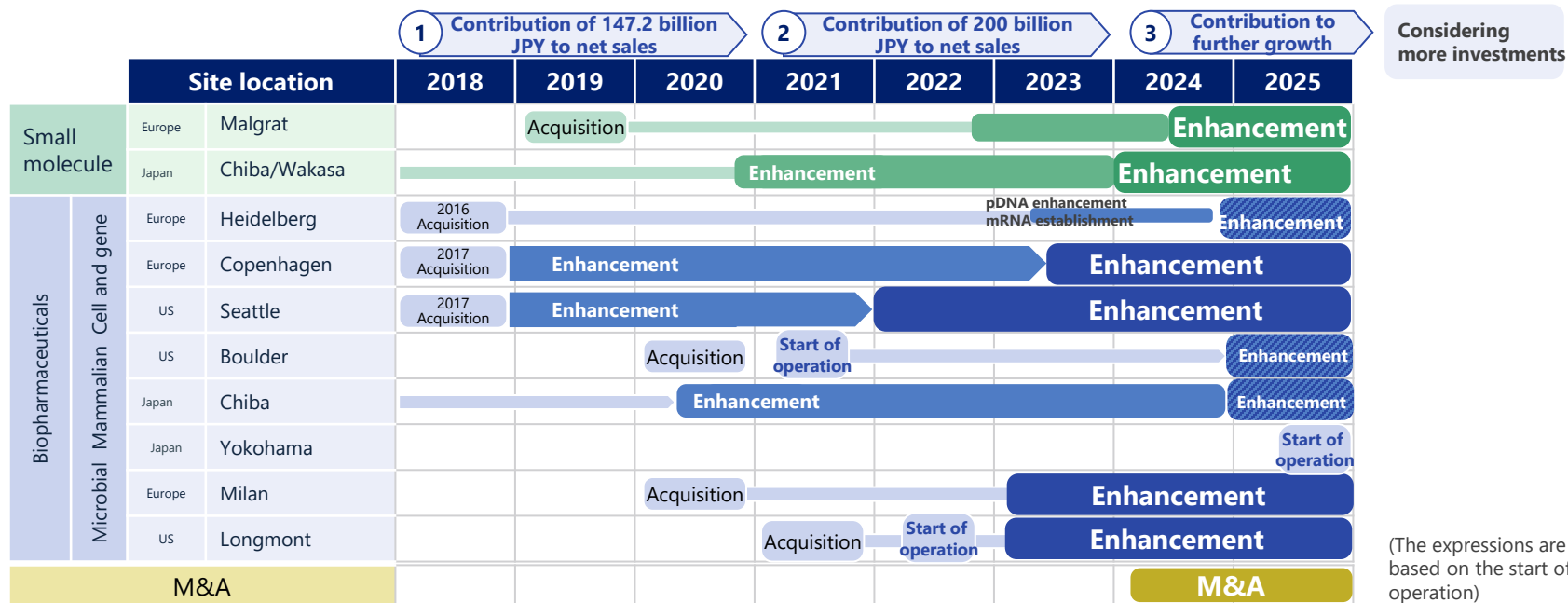
\*\*Source: Exosome Diagnostics and Therapeutics: Global Markets, December 2021, BCC Publishing

# Capacity Expansion (Acquisitions and Facility Expansions)

1 Active investments leading to the achievement of initial goal 4 years earlier than originally planned **and net sales reached 1,472 hundred million JPY in FY2022.**

2 **Investments necessary to reach revenues of 2,000 hundred million JPY already decided.** Investments carried out since 2020 coming online.

3 **Further M&As and Expansions** being considered for further growth.

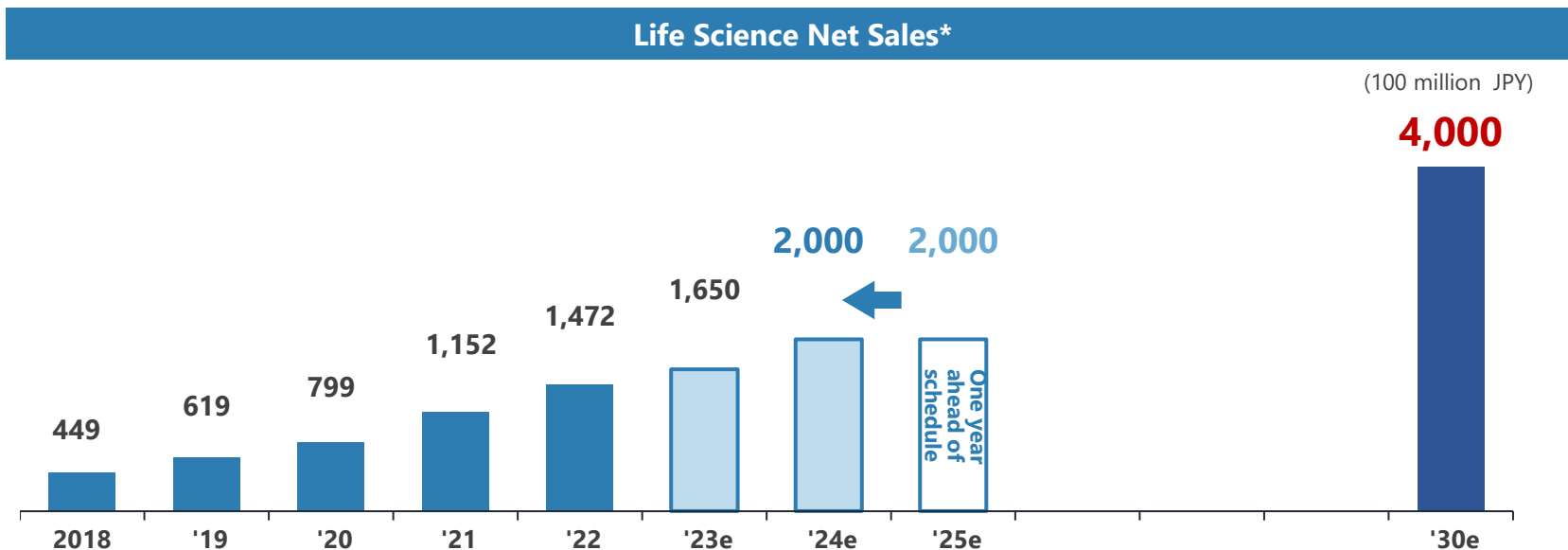


Considering more investments

(The expressions are based on the start of operation)

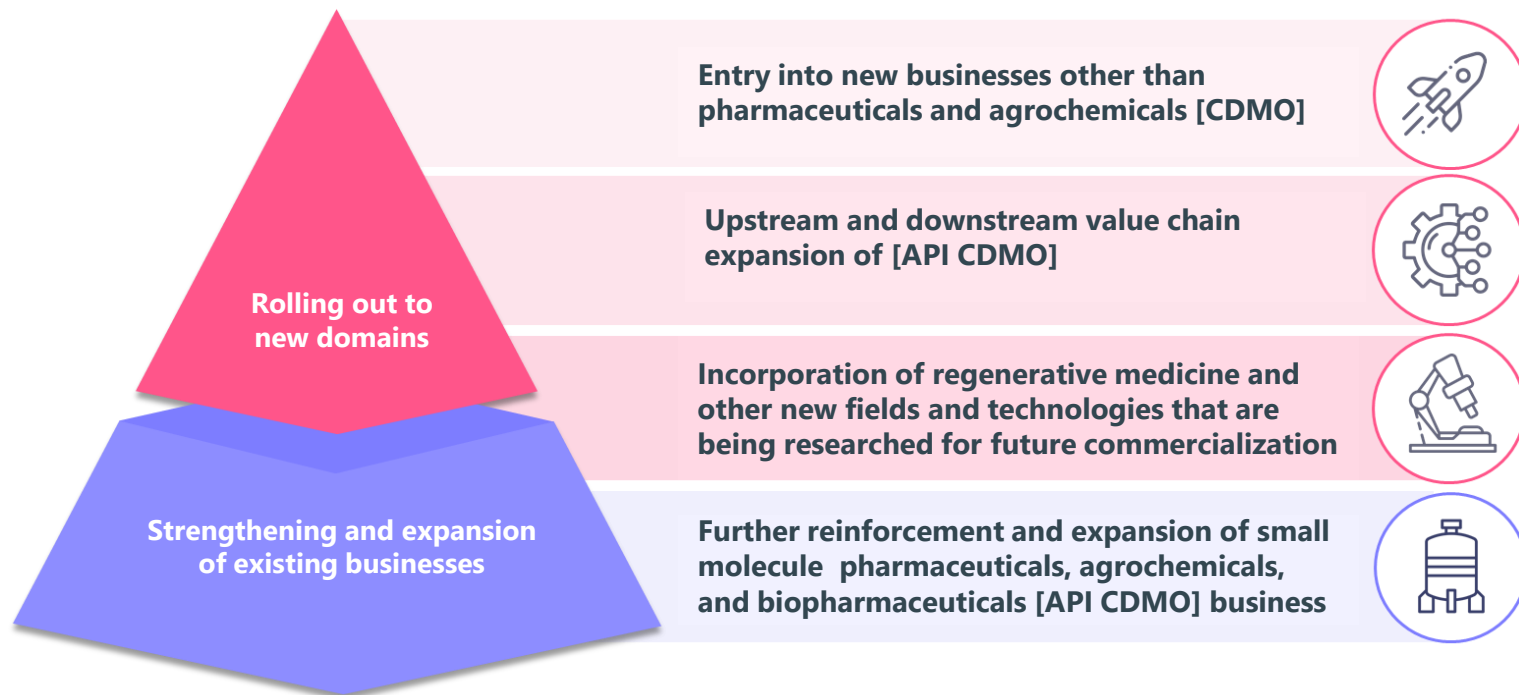
# Medium- to Long-term Performance Targets

- Aiming to achieve sales of **400 billion JPY in 2030**
- Aiming to achieve sales of 200 billion JPY in 2024, one year ahead of schedule



\*Life Science Sales as Strategic Business

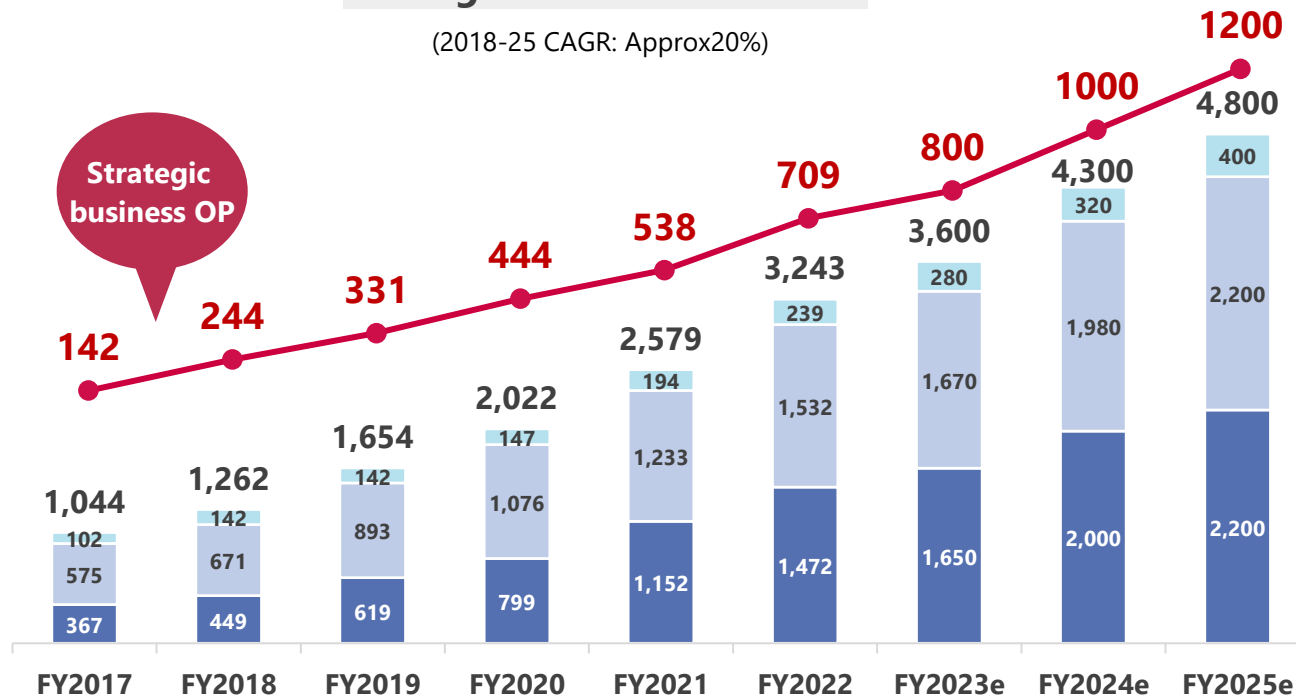
- We will further strengthen and expand our core small molecule pharmaceuticals, agrochemicals, and biopharmaceuticals CDMO business, while also considering expansion of services and business areas when the timing is right.



# Appendix

## Strategic business net sales (100 million JPY)

(2018-25 CAGR: Approx20%)



### Main products & businesses

#### Mobility

- Cover glass for car-mounted displays
- New materials for mobility, including 5G communications

#### Electronics

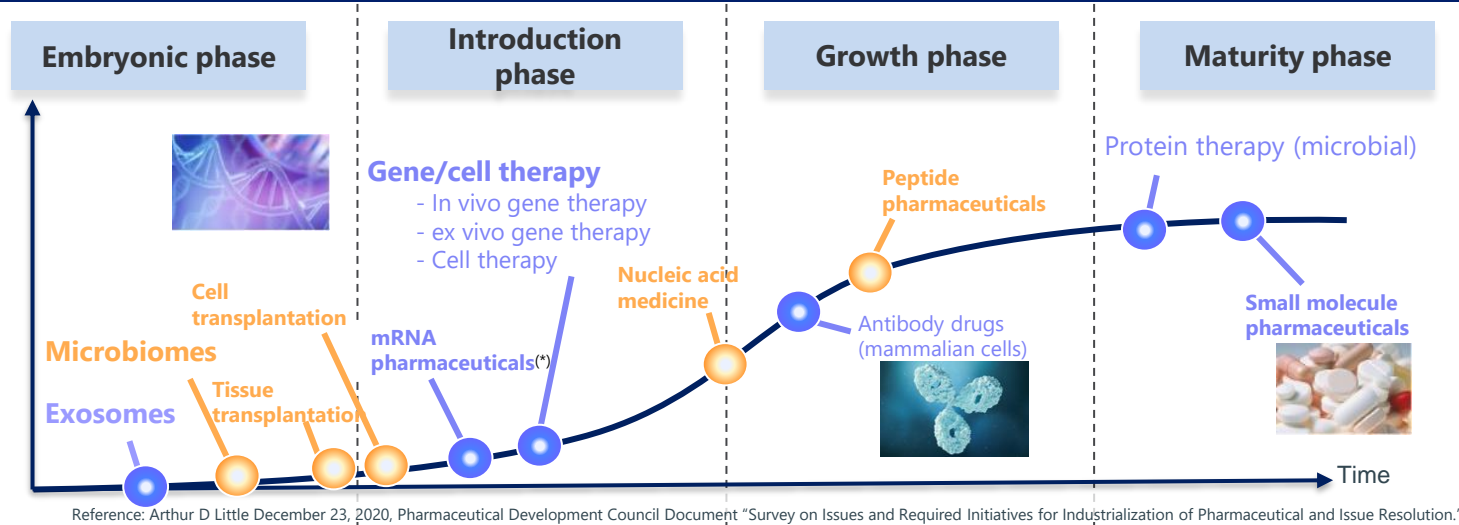
- Semiconductor-related products
- Optoelectronics materials
- Next-generation high-speed communication related products
- Fluorinated products for electronics

#### Life Science

- Synthetic pharmaceutical and agrochemical CDMO
- Biopharmaceutical CDMO
- Other life science products



# Business Strategy according to the Maturity of Pharmaceutical Manufacturing Technology



Exploring and identifying promising new fields and preparing for commercialization

- Establishing a manufacturing platform
- Three global regions
- Rapid establishment of service platform
- Track record in contracted services

- Improvement of customer experience
- Aggressive capacity expansion
- Increase in the proportion of commercial products

- Capacity expansion in line with market growth
- Improvement of operations

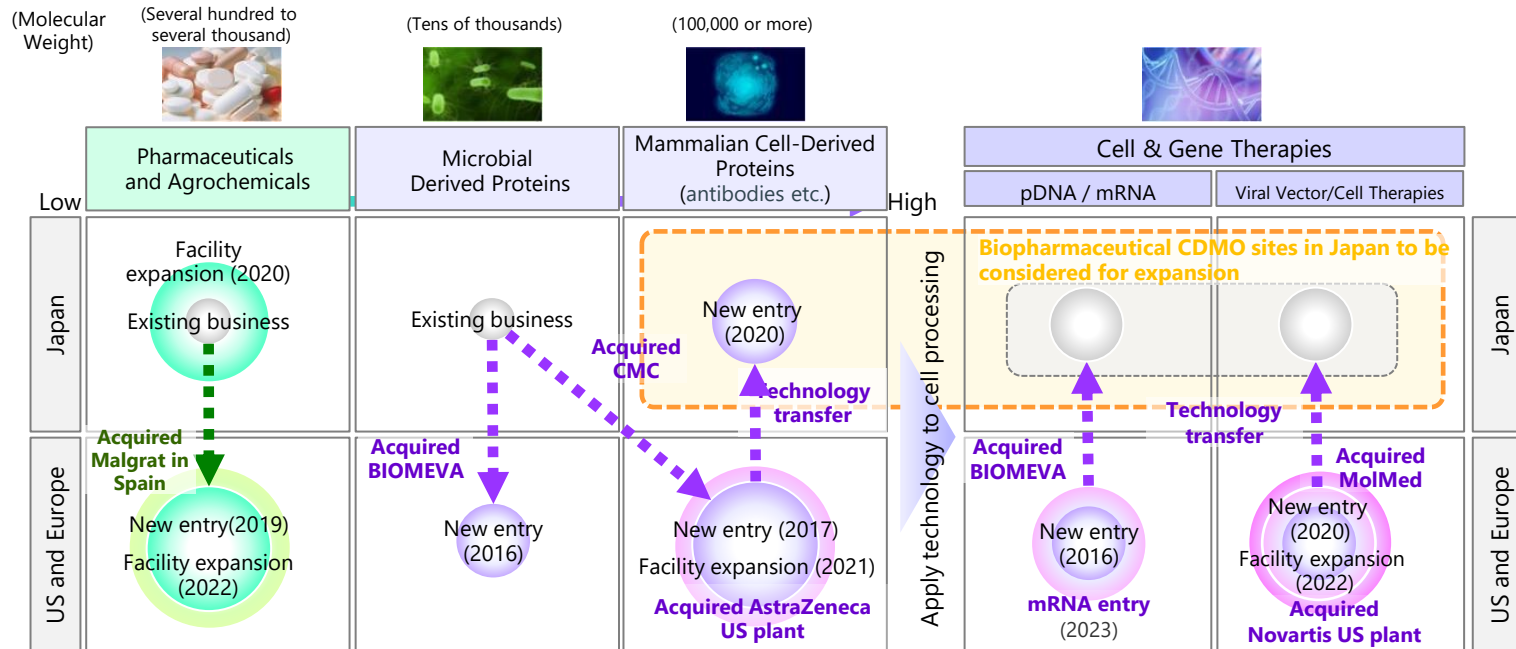
: Pharmaceutical manufacturing technology provided by AGC

(\*) mRNA pharmaceuticals from 2023

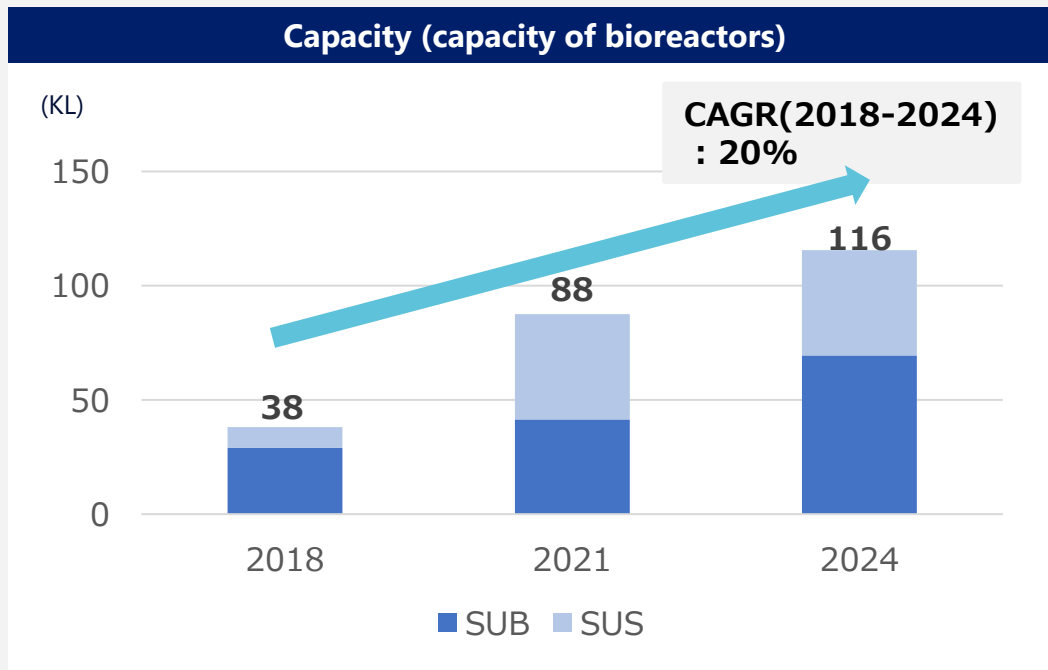
: Next-generation technologies to be considered for entry in the future

# Regional/Technological Expansion of Existing Businesses

- Since 2016, AGC has expanded its business regionally and technologically through aggressive capital expenditures and M&A in overseas companies with superior biotech production technology, forming a solid foundation as a pharmaceutical CDMO.
- Building on this foundation, we plan to continue strengthening our manufacturing capacity (introducing new technologies and increasing manufacturing capacity).

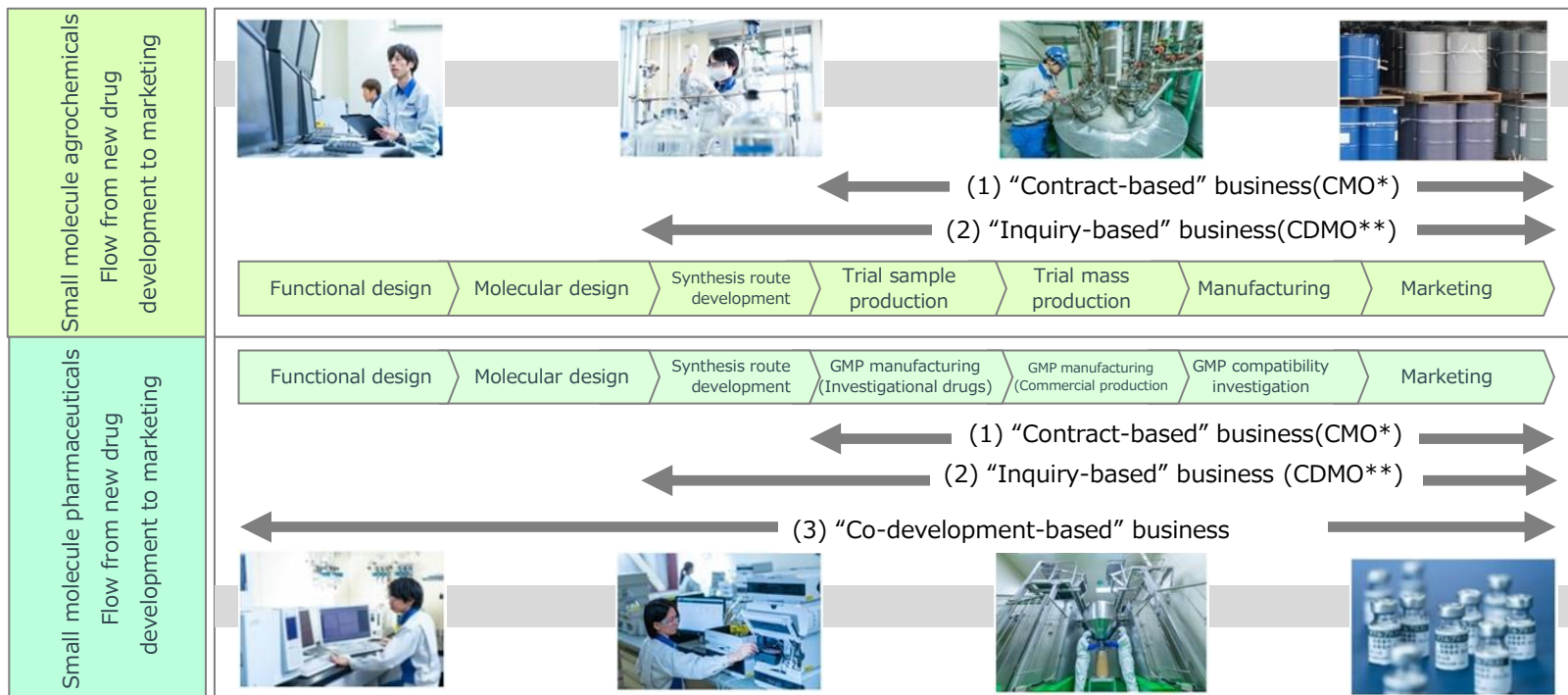


# Capacity Expansion (Mammalian)










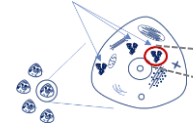

# Life Science Business Scope (CDMO Services for Small Molecule Pharmaceuticals and Agrochemicals)

- Integrated production of raw materials, intermediates and APIs using fine organic chemistry technologies
- Efficient process development to enable low-cost, industrial-scale manufacturing of intermediates and APIs



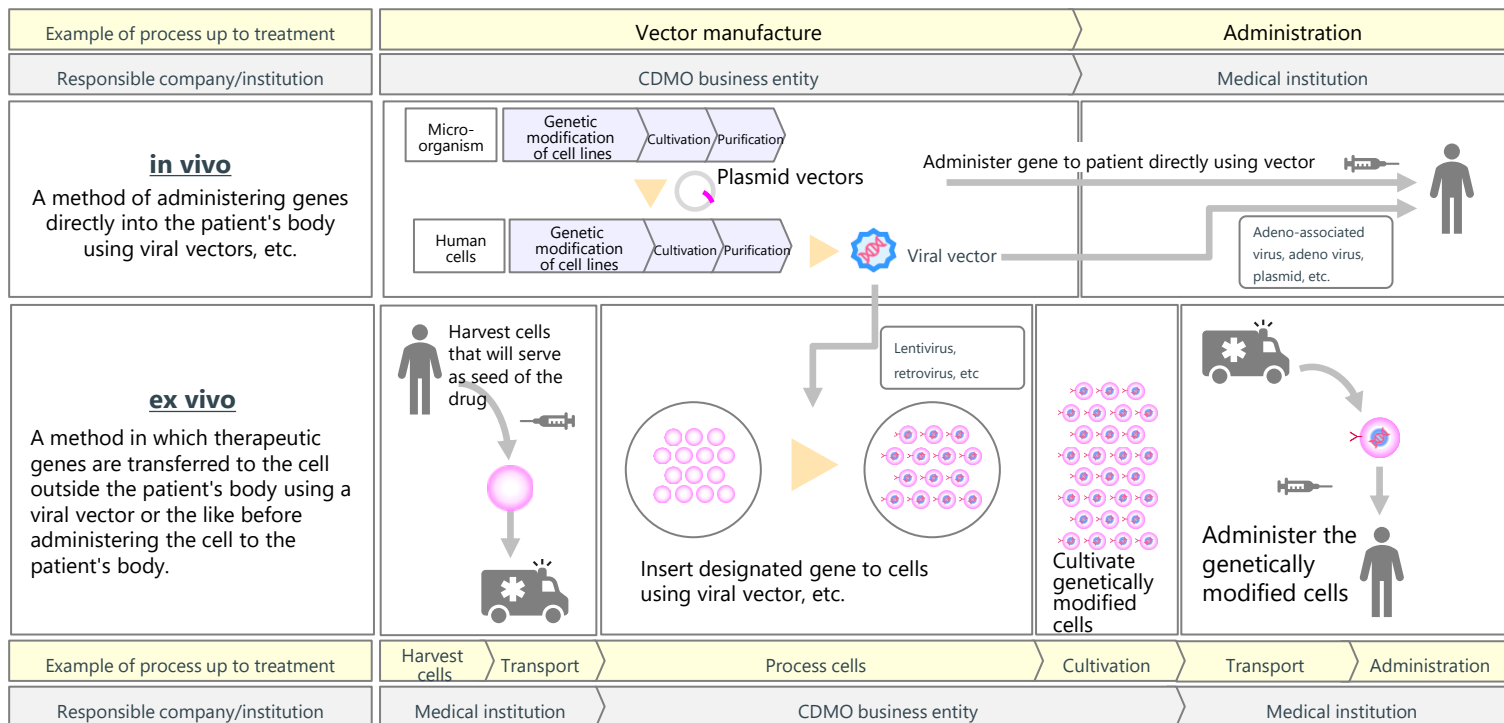
# Life Science Business Scope (CDMO Services for Conventional Biopharmaceuticals)

- 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	Gene recombination	Culture	Harvest	Purification	Finishing into Product/Marketing
	Introduce a recombinant gene into microorganisms/cells.	Increase microorganisms/cells carrying the recombinant gene. At the same time, the target protein (drug) also increases.	Collect and purify the target protein (=drug substance)	-	-
Responsible manufacturer	Pharmaceutical company or contract manufacturer (e.g. AGC)				Pharmaceutical company
(1) Microbial	<p>Recombinant gene (=the seed of the target protein (=drug substance))</p> <p>Microorganism</p> <p>Size: several <math>\mu\text{m}</math> Structure: simple</p>  	<p>Target protein</p>  	<p>Molecular weight: in the order of <math>10^4</math> Structure: simple Drug examples: insulin (anti-diabetic) GCSF(anti-neutropenic)</p>  <p>Target protein (drug substance)</p> 	-	-
(2) Mammalian cell	<p>Recombinant gene (=the seed of the target protein (=drug substance))</p> <p>Size: <math>\geq 10 \mu\text{m}</math> Structure: complicated</p> 	<p>Target protein</p> 	<p>Molecular weight: <math>\geq 10^5</math> Structure: complicated Drug examples: antibodies (e.g. anti neoplastics, anti-rheumatics), EPO (anti-anemic)</p>  <p>Target protein (drug substance)</p>	-	-

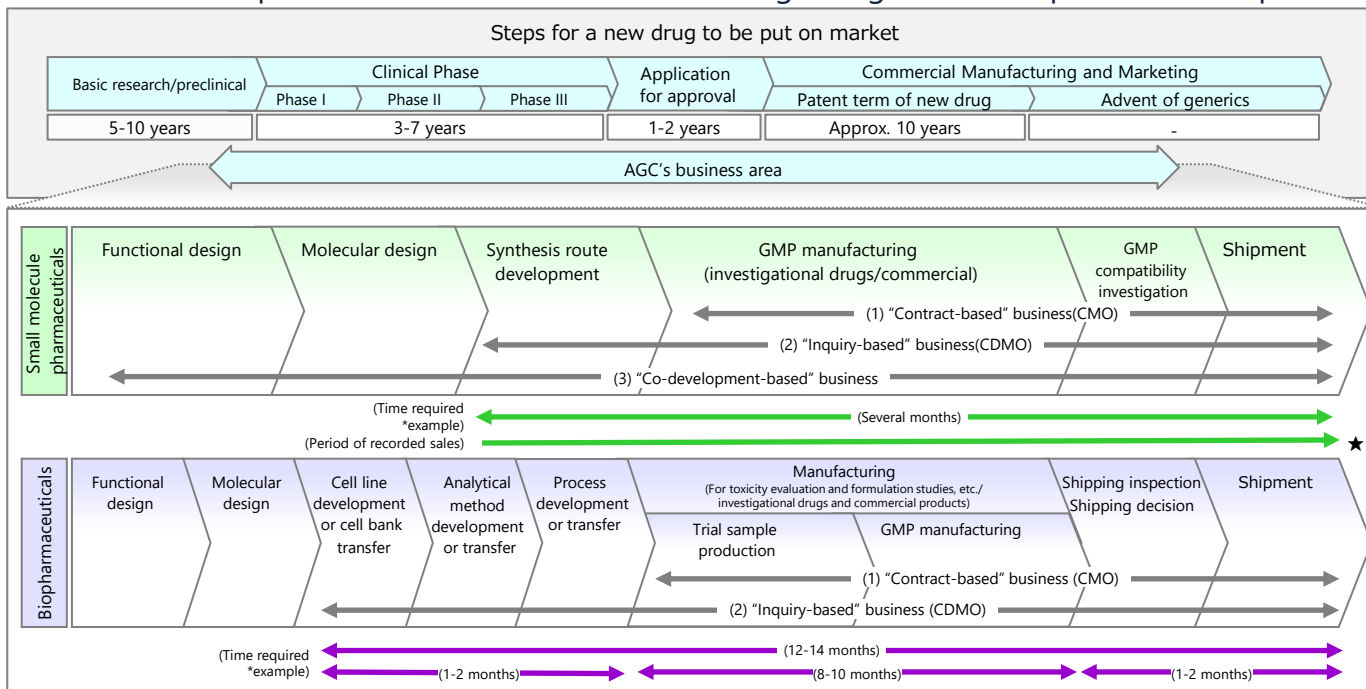
# Life Science Business Scope (CDMO Services for Conventional Biopharmaceuticals)

- In gene/cell therapy, there are many common basic technologies 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.



# Drug Development and the CDMO Business Model

- Contract-periods for biopharmaceuticals tends to be longer with a contract period of two to three years compared to small molecules that could be as short as a few months. Revenue recognition is generally made at each stage and upfront payment is established in many regions, therefore the long contracts do not lead to income instability.
- There are short contracts for biopharmaceuticals as well, when for single stages such as “process development”.



# END

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**AGC**

Your Dreams, Our Challenge