



**AGC Inc.**

Life Science Business Briefing Session

May 31, 2023

## Event Summary

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<b>[Company Name]</b>	AGC Inc.
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<b>[Event Name]</b>	Life Science Business Briefing Session
<b>[Date]</b>	May 31, 2023
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<b>[Time]</b>	17:00 – 18:02 (Total: 62 minutes, Presentation: 25 minutes, Q&A: 37 minutes)
<b>[Venue]</b>	Webcast
<b>[Number of Speakers]</b>	2 Noriyuki Komuro Chikako Ogawa President of Life Science Company General Manager of Corporate Communications & Investor Relations Division

# Presentation

**Ogawa:** At this time, we'd like to start the Life Science business briefing of AGC Inc. I'd like to act as a moderator. My name is Ogawa, Corporate Communications and IR Division. Let me introduce the participants from AGC. We have Mr. Noriyuki Komuro, the Managing Executive Officer and President of Life Science Company.

First, Mr. Komuro will present the business strategy for the Life Science Company, and then we will have a Q&A session. We plan to end at 6:00 PM. I hope you will cooperate with us. If you have any questions, please use the Q&A function. I'd like to hand the microphone to Mr. Komuro.

**Komuro:** Thank you very much for joining us despite your very busy schedule. Let me get started with the Life Science business briefing.



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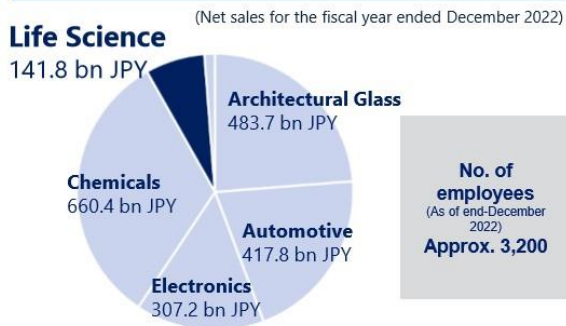
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I'm sure that you have seen this several times, but within AGC Group, as you can see here, we have Core businesses and Strategic businesses. We have what we call ambidextrous management. The Life Science Company is one of the three Strategic businesses. From the AGC Group, high growth and a high level of profits are expected from the Life Science Company.

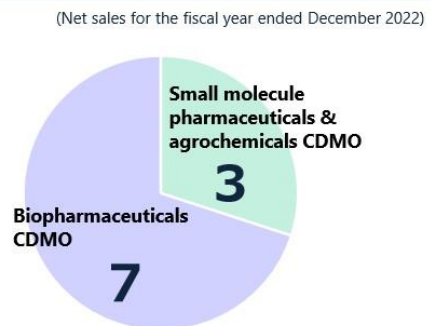
# Establishment of Life Science Company

- 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



## Breakdown of major services in the Life Science Company



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

Let's go to the next slide. Because of that, in 2023 this year in January, as you can see here, the Life Science Company was established. Until last year, it was within Chemicals, and it was one of the divisions. But this year, we have become the Life Science Company. As you can see at the bottom left, last year, Life Science Company sales were JPY141.8 billion. It's about JPY2 trillion as the AGC Group, so about 7% of the total sales is what we have in Life Science Company.

As you can see, the number of employees globally is about 3,200. The Life Science Company, mainly, as you can see on the right-hand side, biopharmaceuticals using biology and the second is the small molecule pharmaceuticals and agrochemicals CDMO business. Those are the two major businesses that we have. The sales, as you can see, bio is 70% and the synthetic small molecule pharmaceuticals and agrochemical is about 30%.

# History of AGC's 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

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 tafuprost, 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))

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Starting this year, we became the Life Science Company, but as you can see on this page, in AGC, life science as a business has a history dating back to 1973. About 50 years ago, we started to focus on life science and started our business. On the left-hand side, we have the small molecules synthetic, and on the right-hand side, we have biopharmaceuticals.

On the left-hand side, in synthetic pharmaceuticals in 1985, the CDMO contract development manufacturing organization business started. In the biopharmaceutical area in 2000, biopharmaceuticals CDMO business started. AGC has been in the life science business, probably you did not recognize that, but inside the company, we do have quite a long history. During those years, we have developed and bolstered this life science business.

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This is a new slide, which is not included in your materials. From now on, the strength of AGC Life Science, I will start talking about that.

But before I do that, the Q1 results, which were announced recently are shown here. There were many questions on this, so I'd like to briefly explain the quarterly Q1 results. After the brief explanation, I'd like to go into the Life Science business itself, so that's why I'm showing you this slide.

As you can see, Q1 compared to last year, the sales were the same and operating profit was significantly down, and we received many questions on this point. The reason is that as you can see, the COVID-19-related special demand is now gone. Of course, we are offsetting that with other businesses, so the sales remained at the same level as FY2022. The major growth of sales came from the new US plant. Because of that, the new plant fixed cost is high. In terms of sales, it was up or increased, but more than that, the fixed cost was higher. That is the part which brings down our operating income.

With the startup of a new plant, there were some glitches or issues. That was one of the reasons why the profits were down. The new plant is starting up, we are struggling with it. But in Q2 and onwards, we expect to make improvements, and if the startup goes well from now on, for one year this year, if you look at the full year, probably we would see not a major change. The full-year forecast for this year is not changed at this moment.

Now, let me talk about the strength of AGC Group.

# 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.**



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The biggest characteristics that we have, or the strength is, as you can see here, in US, Europe, and Japan, in three regions, we have 10 sites. In those sites, we have high level of services that we are providing at the same time. In those three regions, what we are showing, you see the list of plants and factories. Originally, in the area of biopharmaceuticals, the microbiome business was what we had.

Then the mammalian technology was acquired, and then gene and cell therapy were acquired. For those M&As, we gained the technologies, and we apply those technologies to other areas. More specifically, in 2017, we acquired CMC, and the mammalian technology that we obtained was applied to Chiba, in Japan. In Milan, we have acquired the gene and cell therapy technology, and now, this is applied in Longmont, the United States. In Yokohama, we are planning the next plant. The new modalities, high growth modalities are the ones that we acquire and quickly deploy to different regions or different sites in the world. Basically, that is our growth strategy.

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



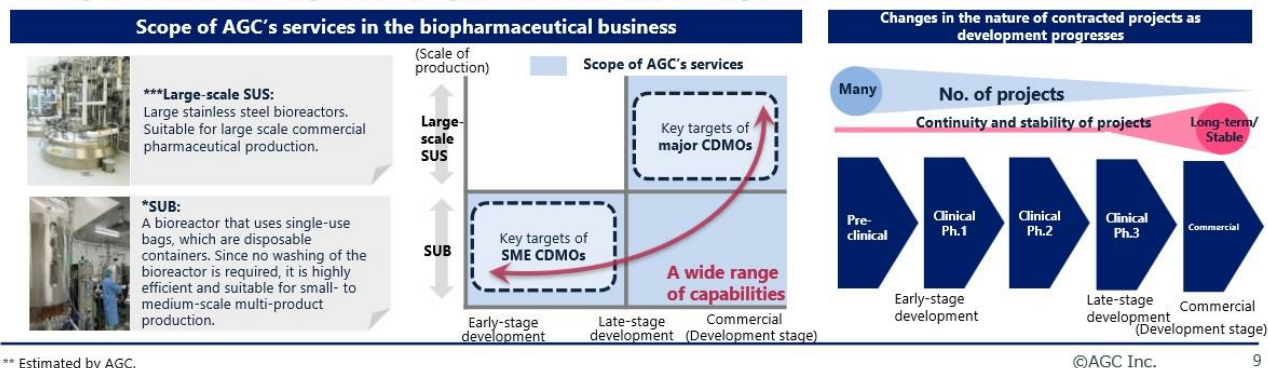
### ■ Addresses a wide range of production scale needs that change as development progresses

-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.



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This is our strategy. We have a flexible production system. In order for you to understand this, it will require a basic explanation. At the bottom right, if you look at the increase of the number of projects, this shows the process of pharmaceutical development. Starting with the preclinical and going through Phase I, II, and III, and then getting the approval from the regulator and go to the commercial stage.

Naturally, as you progress in the process, the required volume of the pharmaceuticals will increase and also the quality management level will also get higher. As it says here, at the top point, the synthetic pharmaceuticals at the beginning, early stage, the volume of manufacturing is at the low level, so we'll focus on that, so small scale bio-facilities are necessary. Then after the approval, this would be delivered to the patients in the world. For that, we need a bigger facility. From the small scale to the scale reactors, we have all of them.

It's the same for biopharmaceuticals as well. Initial phase towards the middle, we have these single-use bags. Those will be small bioreactors.

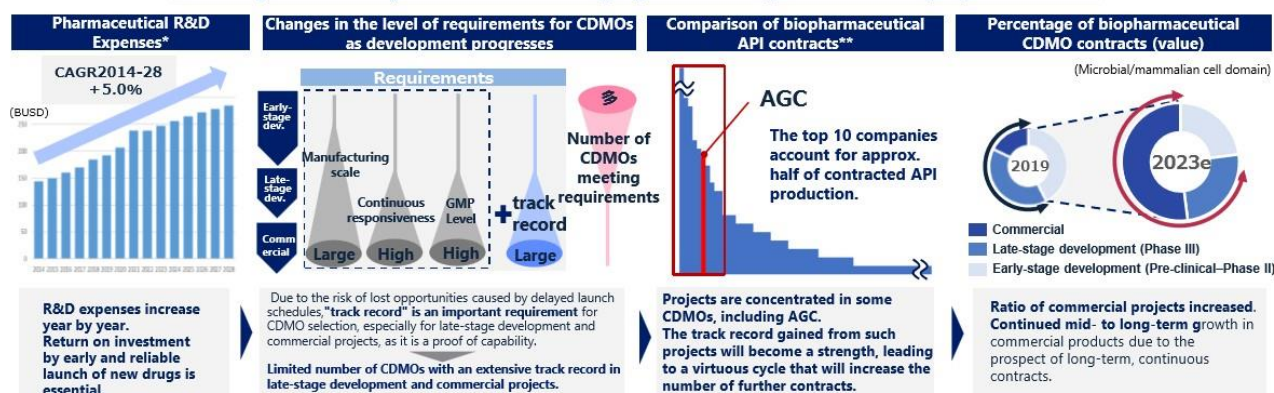
That means after each use, you only need to clean and reuse, but now the single-use bags are only used once. It allows for a lot of small batch production. We have a great capacity. We are at the second part of single-use bags biopharmaceuticals. The largest one we have is China. But if you look at the Europe, we are the first. We have a new facility in Copenhagen. We are by far the largest in that area. We are still number two, but we're much ahead of number three. If we look at the middle chart in the bottom, you can think that now we can start with the early phase development and commercial. After late stage have taken place, they would be in larger production batches, and we have SUS in US. We are able to meet those different needs and different scales of production, and that's our advantage.

### 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.



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

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

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Next, please. Particularly, we are building our track record with the commercial and enlarged by pharmaceutical businesses, and you can see that here.

The second chart, there will be more stringent requirements in the quality, once you are that late stage and commercial. The level of trust and confidence our customers are requiring. That also leads to more contrast given to us, so there is this virtuous cycle running.

On the right-hand side, because of that, and as I said earlier, once we go to a later phase and go to production, we are now having a larger percentage of commercial phase production. It's different from the early-stage development movement, because a certain percentage would not advance in the early-stage. That means we have certainty and more duration of each and every contract as we have more from a later stage or commercial phase.



## 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**.



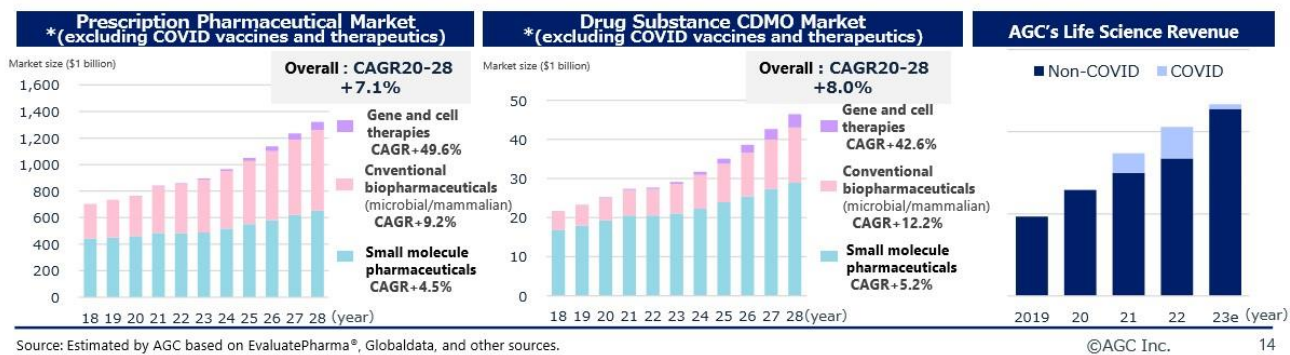
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In particularly with regards to small molecule with an environment conservation, Ecovadis gave us very high rating. This indicate that we are the outstanding environmentally friendly supplier.

## Current Situation and Outlook (1/2)

Current	<p><b><u>Disappearance of extraordinary demand related to COVID:</u></b> Due to changes in the global pandemic, extraordinary demand related to COVID has run its course. Contracts for COVID-related products declined.</p>
Future	<p><b><u>Acceleration of non-COVID projects:</u></b> 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.</p>



Source: Estimated by AGC based on EvaluatePharma®, Globaldata, and other sources.

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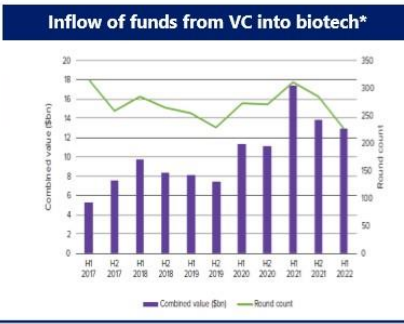
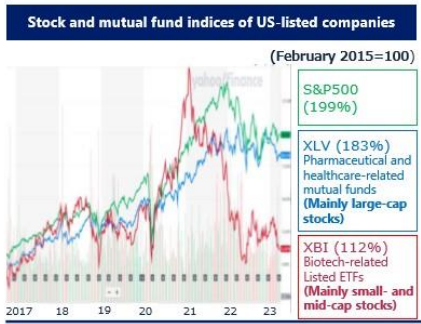
We have a flexible production system, and with our good track record, we are getting additional orders. Also, as a CDMO, we are focused on a sustainable business as well. Let's look at the business environment. Earlier, I touched upon this. But once again, I'd like to talk about our recent business environment briefly. What you see on this slide, the COVID-19-related special demand is now gone, and bottom right, our life science sales trend is showing the non-COVID-19 and COVID-19 breakdown. Until last year, as you can see here, the COVID-

19-related special demand was what we had. But this year, there are some remaining, but it's almost gone. We are offsetting this with non-COVID-19 growth.

What we expect here is as follows. As you can see on the left-hand side, what we do is the synthetic pharmaceutical and biopharmaceutical and the gene and cell therapies. Those three areas that we focus upon. With or without the COVID-19, in coming years, we expect those three to continue to grow. As you can see, that is our expectation.

## Current Situation and Outlook (2/2) AGC Your Dreams, Our Challenge

<b>Current</b>	<p><b>Slowdown of early-stage development projects from SME biotechs:</b> 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.</p>
<b>Future</b>	<p><b>Building a business structure that is resilient to the economy and other factors:</b> 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.</p>



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

\*\*source : Globaldata and AGC estimate ©AGC Inc. 15

The capacity that we have right now and track record, and with that, we'd like to continue to expand our businesses. However, having said that, in the long run or medium term, that is what we expect. But in the short term, currently, the biotech investment inflow has been slowing down. As you can see at the bottom on the left shown in red, stock prices have been at low level.

From the customers, the funding difficulties are mentioned. In comparison to the plan that they had, there have been some delays or adjustments. For example, out of five projects, they are reducing it to three projects. We are starting to see such phenomena. As I said, for this year, the impact of that is something that we are watching very closely, and we have to be very careful about that.

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



### 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.

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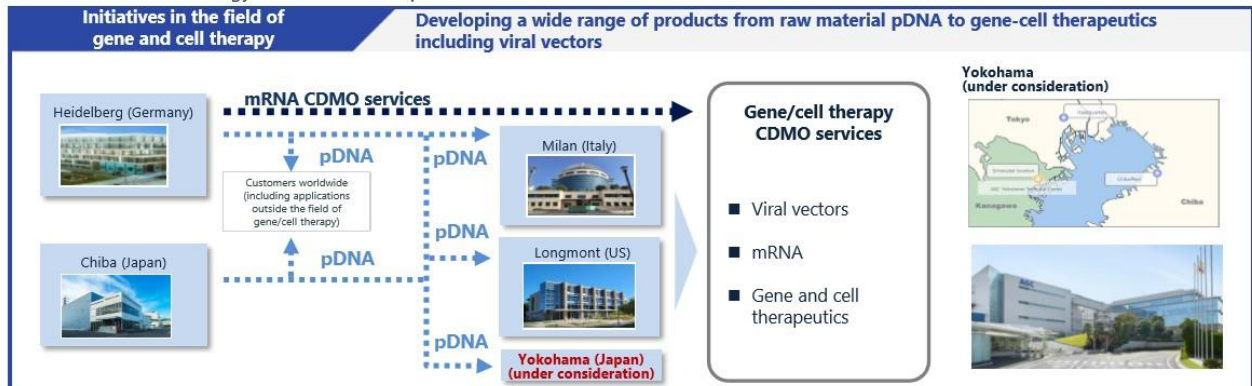
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Now, I'd like to talk about future business and growth. As I mentioned earlier, in each business area, we expect growth. For that, we are taking those measures. First of all, starting with synthetic pharmaceuticals. In this area, our position is that rather than market share, we are in the niche area, so we want to make sure that we can utilize our strength to expand our businesses. That is our basic way of thinking. But still, gradually, pharmaceuticals are becoming more advanced and structurally complex and difficult. Because of that, as you can see here, increasing the expansion in 2020 to about 10x or 1.3x in Spain, 1.5x in Fukui Japan, gradually and steadily, we are going into the areas that require high level of technologies.



## 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.



\*AGC estimates.

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For biopharma, again, as I mentioned, we are focusing on our three regions. We are now trying to expand the biopharmaceutical CDMO capacity in Japan. Particularly as we showed earlier, we have the CAGR, which is large for gene and cell therapy. After we acquired Milan, we also have a long month in the United States; that's one site we have there. We are intending to add another site in Japan, in Yokohama. Currently, we are setting that possibility.

# 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.

Cells on the secretion side      Cells on the reception side

### Exosome market size trend\*\*

Overall : CAGR19-26 + 39%

Research tools CAGR+23%  
Therapeutics CAGR+38%  
Diagnostic agents CAGR+41%

### Partnership with RoosterBio

Knowledge and results related to hMSCs, culture media, and exosomes

Knowledge and experience in bioprocess-related manufacturing, scaling up, GMP compliance, etc.

\*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

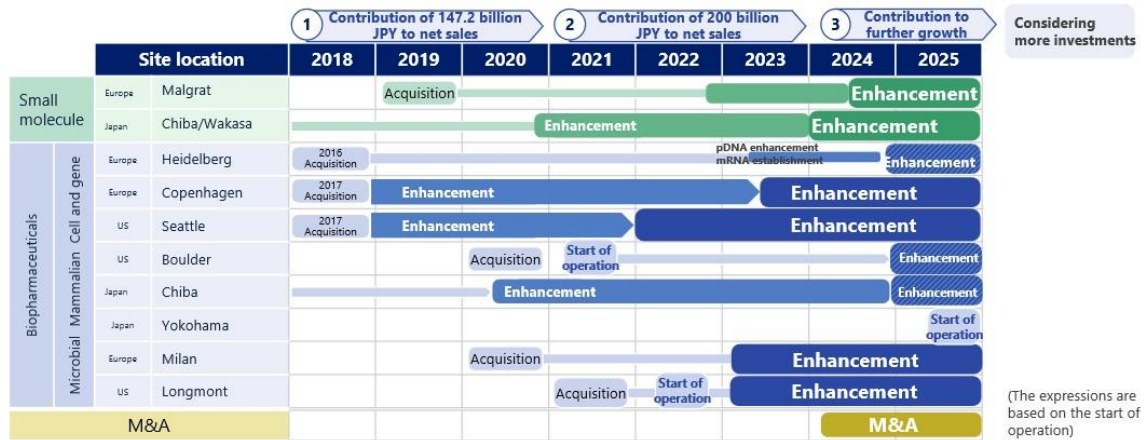
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The next slide is just for your information. We are considering for gene and cell therapy and then for new fields and new technologies in Yokohama site. As one example, we are focusing on the possibility of exosome CDMO. We are actually beginning this already. For our strategy, with regards to growth, we are trying to introduce new services that have a large growth potential, and that will be rolled out globally. That's our basic strategy. One example is this using exosome pharmaceuticals, once the market has right to size, we can roll out that operations globally.

# 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.



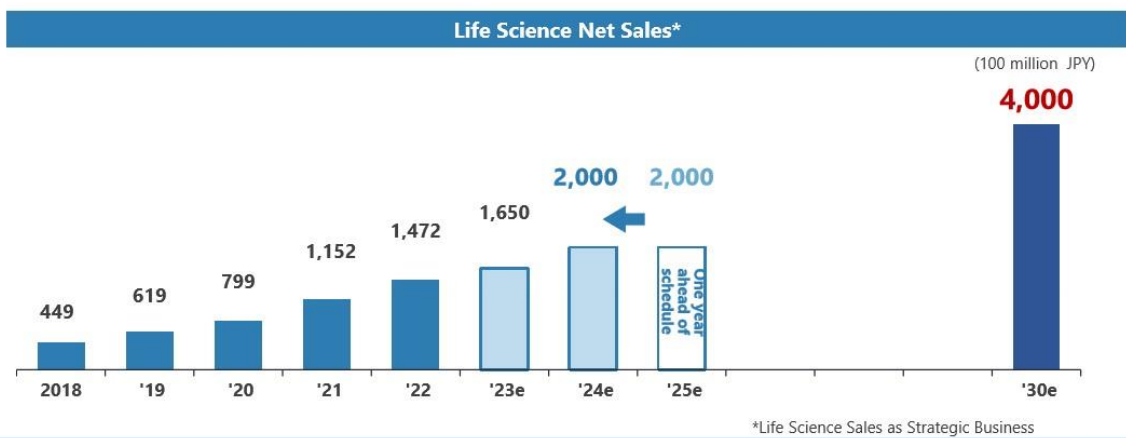
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This is the summary chart of what I've already introduced. I won't be able to go into every detail here on this chart. For example, if you look at number two, this is about getting JPY200 billion in sales. The investment necessary has already been added. With the existing capacity, we are very well capable of getting to sales of JPY200 billion. For further growth, we will have to add to this. As you can see, from 2024 and onwards, we are considering further capacity expansion as well as M&A.

## Medium- to Long-term Performance Targets **AGC** Your Dreams, Our Challenge

- 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



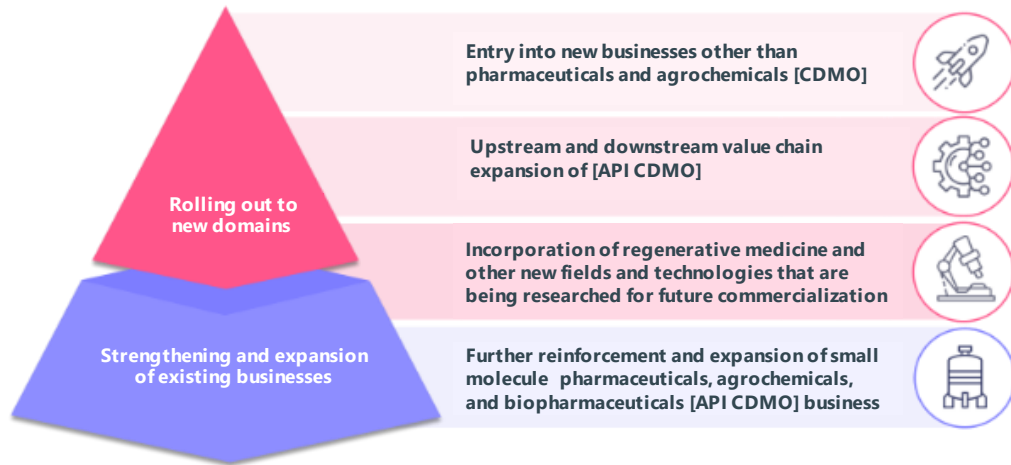
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Based on what I've already explained, by 2030, we are trying to achieve sales of JPY400 billion. We believe that it's very doable.

- 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.



I talked about this JPY400 billion in sales, and that's really based on the blue part of the charts, strengthening and expansion of existing businesses. We are also trying to now look at new domains. That's the top part. It's not just pharmaceutical CDMO, but other areas. We are currently only in the blue part, but we would think about further upstream and downstream or more actual drug products.

That concludes my brief presentation. Thank you very much for your kind attention.

[END]