Life Science Business

AGC Inc.

June 25, 2019

Your Dreams, Our Challenge
Content of today’s presentation

1. Life science business of AGC - positioned as one of the strategic business of AGC

2. Macro business environment

3. CDMO business of AGC

4. Requirements for CDMOs and AGC’s efforts
1. Life science business of AGC

- positioned as one of the *strategic business* of AGC
AGC Group’s long-term strategy

“Vision 2025”

The AGC Group’s Core Businesses will serve as solid sources of earnings, and Strategic Businesses will become growth drivers and lead further earnings growth. The AGC Group will continue being a highly profitable, leading global material and solution provider.

Core businesses

Establishing long-term, stable sources of earnings through the portfolio management

- Architectural glass
- Automotive glass (existing)
- Essential chemicals
- Performance chemicals
- Display glass
- Ceramics

Strategic businesses

Establishing highly profitable businesses through expansion of high value-added businesses

- Mobility
- Electronics
- Life science
Strategic Businesses
Highly profitable businesses with growth potential

【Changes in the macroscopic environment】

Arrival of IoT era
Evolution of transportation infrastructure
Building new eco-system

Longer life expectancy
Increase of global population
Greater safety, security, comfort

Mobility
Connected cars/
Automated driving,
Evolution of information
display, Lighter-weight
transportation means

Electronics
Arrival of IoT/AI era,
Next-generation high-speed communications/
Automated driving, Use of
novel devices

Life Science
Safe & secure medical
care, Longer life
expectancy, Increase of
global population

Strategic Businesses
Future Growth by Strategic Businesses category

- Electronics and Life science will start generating profit first.
- Mobility will gradually produce results after FY2021.

Sales (Strategic business) (100 m yen)

<table>
<thead>
<tr>
<th>FY2017</th>
<th>FY2018</th>
<th>FY2019e</th>
<th>FY2020e</th>
<th>FY2025e</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mobility</td>
<td>1,050</td>
<td>1,250</td>
<td>1,450</td>
<td>1,750</td>
</tr>
<tr>
<td>Electronics</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Life Science</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Major products & business
- 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
  - Bio CDMO

<table>
<thead>
<tr>
<th>OP (Strategic business)</th>
<th>FY2017</th>
<th>FY2018</th>
<th>FY2019e</th>
<th>FY2020e</th>
<th>FY2025e</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contribution ratio</td>
<td>120</td>
<td>210</td>
<td>280</td>
<td>400</td>
<td>900</td>
</tr>
<tr>
<td></td>
<td>10%</td>
<td>17%</td>
<td>22%</td>
<td>25%</td>
<td>40%</td>
</tr>
</tbody>
</table>

(100 m yen)
2. Macro business environment
Worldwide Prescription Drug Sales Forecast

Worldwide Total Prescription Drug Sales (2010-2024)

2018-24 CAGR

- Bio pharmaceutical: 8.9%
- Synthetic pharmaceutical and others: 5.2%
- Total: 6.4%

Source: Chart made by AGC based on data from EvaluatePharma® World Preview 2018, Outlook to 2024
AGC’s business area in the flow of new drug development

- Our business area covers up to the contract development/manufacture of the “active pharmaceutical ingredient (API)” of a drug used in the “clinical study” and subsequent stages.

<table>
<thead>
<tr>
<th>Basic research/preclinical</th>
<th>Clinical studies</th>
<th>Application for approval</th>
<th>Manufacturing/Marketing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discovery and screening of new candidate substances for drugs, evaluation of the properties and safety of such substances in animals</td>
<td>These studies are also referred to as &quot;clinical trials&quot; and performed in human subjects, usually following the above 3 steps</td>
<td>Approval is granted by the Minister of Health, Labour and Welfare after confirmation of the efficacy/safety of the drug</td>
<td>The product is manufactured and marketed as a new drug. After expiration of the patent term, generics (biosimilars) will be allowed to enter the market.</td>
</tr>
</tbody>
</table>

5-10 years | 3-7 years | 1-2 years | ~10 years

Provision of services related to API manufacturing

AGC Biologics (Denmark)

AGC Biologics (Chiba Bio Plant)

AGC’s business area

Raw materials → Intermediate** → API* → Drug product

Drug product

AGC’s business area

Genetic transformation → API manufacturing → Drug product

AGC’s business area

* API (the active ingredient of a drug), ** Intermediate (a product that requires one more reaction step before it becomes a drug substance)
### Trend of the pharmaceutical companies

- Global trend is to sell manufacturing plants, including Japan. Current trend is also to outsource or sell in-house functions, such as logistics.

<table>
<thead>
<tr>
<th>Year</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>plant</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>May 2011</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nippon Shinyaku</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chiba plant (synthetic): Sold</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mitsubishi Tanabe Pharma</td>
<td>Astellas</td>
<td></td>
<td>Mitsubishi</td>
<td>Astellas</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ashikaga plant Sold</td>
<td>Fuji plant: Sold</td>
<td></td>
<td>Tanabe Pharma</td>
<td>Kiyosu plant: Sold</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Kashima plant: Sold</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shionogi</td>
<td>Mitsubishi Tanabe Pharma</td>
<td>Daiichi Sankyo</td>
<td>Kyowa Kirin plus</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outsourced</td>
<td>logistics of MP logistics</td>
<td>logistics center</td>
<td>Kyowa Hakko Kirin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Logistics</td>
<td>Outsourced</td>
<td>assigned</td>
<td>logistics subsidiary</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
A large portion of the global clinical pipelines are held by emerging companies

Number of global clinical pipelines (database accessed in April 2019)

- Phase I: Large company 2,438, Emerging company 831
- Phase II: Large company 3,337, Emerging company 1,058
- Phase III: Large company 1,120, Emerging company 151


Source: The chart made by AGC based on data from 2019 Emerging Therapeutic Company Trend Report
Worldwide pharmaceutical CDMO market

- Worldwide pharmaceutical CDMO market was $20.5bn in 2017 and is expected to grow at a CAGR of +7% to $28.8bn in 2022.
- Steady growth is expected for Synthetic pharmaceutical (CAGR 7%) and biopharmaceuticals (9%).

Source: The chart made and estimated by AGC based on data from EvaluatePharma® World Preview 2017, Outlook to 2022
3. CDMO business of AGC

(Contract Development Manufacturing Organization)
Overview of CDMO services/co-development business for synthetic pharmaceuticals/agrochemicals

- Integrated production of raw materials, intermediates and APIs using fine organic synthesis technology
- Efficient process development to enable low-cost, industrial-size contract manufacturing of intermediates and APIs

Flow of new drug development and marketing

- Functional design
- Molecular design
- Synthesis route development
- GMP manufacturing (Investigational drugs)
- GMP compatibility investigation

(1) “Contract-based” business (CMO*)
(2) “Inquiry-based” business (CDMO**)
(3) “Co-development-based” business

* CMO (Contract Manufacturing Organization) **CDMO (Contract Development Manufacturing Organization)
AGC receives the “target gene” from the client and performs the “cultivation”, “isolation” and “purification” processes on a contract-basis.  

The “target protein (=biopharmaceutical)” is produced. The flow of the manufacturing process are the same in both microbial and mammalian cells.

<table>
<thead>
<tr>
<th>Manufacturing process</th>
<th>Genetic transformation</th>
<th>Cultivation</th>
<th>Isolation</th>
<th>Purification</th>
<th>Marketing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Introduce a recombinant gene into microorganisms/cells.</td>
<td>Increase microorganisms/cells carrying the recombinant gene. Then, the target protein (=drug) also increases.</td>
<td>Collect and purify the target protein (=drug substance)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Responsible entity</th>
<th>Pharmaceutical company or contract manufacturing organization (e.g. AGC)</th>
<th>Pharmaceutical company</th>
</tr>
</thead>
</table>

(1) Microbial

- Recombinant gene (=the seed of the target protein [=drug substance])
- Size: several μm
- Structure: simple

- Target protein

- Molecular weight: in the order of $10^4$
- Structure: simple
- Drug examples: insulin (anti-diabetic), GCSF (anti-neutropenic)

- Target protein (drug substance)

(2) Mammalian

- Recombinant gene (=the seed of the target protein [=drug substance])
- Size: ≥10 μm
- Structure: complicated

- Target protein

- Molecular weight: ≥$10^5$
- Structure: complicated
- Drug examples: antibodies (e.g. anti-neoplasticss, anti-rheumatics), EPO (anti-anemic)

- Target protein (drug substance)
### 30-year history of AGC’s life science business

#### Events related to contract development/manufacturing of **synthetic pharmaceuticals/agrochemicals**

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1973</td>
<td>Launched The Life Science Team to investigate the applicability of AGC’s fluorination technology to pharmaceutical/agrochemical production</td>
</tr>
<tr>
<td>1985</td>
<td>Started contract manufacturing/supplying of fluorine intermediates for antibiotic for pharmaceutical companies</td>
</tr>
<tr>
<td>1989</td>
<td>Developed a method for synthesizing activated vitamin D3 and marketed the product after approval by the Ministry of Health</td>
</tr>
<tr>
<td>1990</td>
<td>Started co-development of prostaglandin derivatives with a pharmaceutical company at the request of Prof. Mizushima from St. Marianna University School of Medicine</td>
</tr>
<tr>
<td>2003</td>
<td>Established a GMP-compliant, multi-purpose facility for large-scale manufacturing of investigational medicinal products (CMP building) within Chiba Plant</td>
</tr>
<tr>
<td>2008</td>
<td>Obtained marketing approval for tafluprost, an anti-glaucoma drug substance co-developed with Santen Pharmaceutical</td>
</tr>
<tr>
<td>2013</td>
<td>Doubled the manufacturing line capacity for tafluprost. Established a new plant, Kaminaka Plant, within Wakasa Techno-Valley of AGC Wakasa Chemicals</td>
</tr>
<tr>
<td>2015</td>
<td>Doubled the production capacity of Kaminaka Plant of AGC Wakasa Chemicals</td>
</tr>
<tr>
<td>2019</td>
<td>Acquired Malgrat Pharma Chemicals (Spain) and planning to augment the production capacity of Chiba Plant by 10-fold</td>
</tr>
</tbody>
</table>

#### Events related to contract development/manufacturing of **biopharmaceuticals**

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1984</td>
<td>Formed the Biochemical Group focused on pharmaceutical development within the Research &amp; Development Division</td>
</tr>
<tr>
<td>1997</td>
<td>Developed proprietary high-efficiency/high-speed protein manufacturing technology using Schizosaccharomyces yeast (ASPEX)</td>
</tr>
<tr>
<td>2000</td>
<td>Established a biotechnology-based drug manufacturing facility within the Central Laboratory to formally launch the contract protein manufacturing business</td>
</tr>
<tr>
<td>2000</td>
<td>Established the ASPEX Business Promotion Division to supervise the contract protein manufacturing business</td>
</tr>
<tr>
<td>2008</td>
<td>Established a new plant (ABP building) within Chiba Plant with 10-fold higher capacity for contract manufacturing of biopharmaceuticals</td>
</tr>
<tr>
<td>2016</td>
<td>Acquired Biomeva, a major German biopharmaceutical contract manufacturing organization (CMO)</td>
</tr>
<tr>
<td>2017</td>
<td>Acquired CMC Biologics, a CDMO of biopharmaceutical active ingredients with several manufacturing bases in Europe and US</td>
</tr>
<tr>
<td>2018</td>
<td>Augmented the production capacity in Berkley, U.S. and Denmark and established a new R&amp;D center in Seattle, U.S.</td>
</tr>
<tr>
<td>2019</td>
<td>Planning to establish new animal cell-based manufacturing facilities in Chiba Plant</td>
</tr>
<tr>
<td>2019</td>
<td>Planning to augment the capacity of the mammalian cell-based manufacturing facility in Seattle, U.S. by 3-fold and establish new microbial manufacturing facilities</td>
</tr>
<tr>
<td>2020</td>
<td>Planning to augment the capacity of the mammalian cell-based manufacturing facility in Seattle, U.S. by 3-fold and establish new microbial manufacturing facilities</td>
</tr>
</tbody>
</table>
Business locations

Seattle
(United States)
Acquisition in 2017
Mammalian facilities enhanced in 2019
Microbial facilities to be established in 2019

Copenhagen
(Denmark)
Acquisition in 2017
Mammalian facilities enhanced in 2018

Chiba
(Japan)
Mammalian facilities to be established in 2019
Synthetic pharmaceutical facilities to be expanded in 2019

Heidelberg
(Germany)
Acquisition in 2016

Malgrat
(Spain)
Acquisition in 2019

Fukui
(Japan)

Yokohama
(Japan)

Berkeley
(United States)
Acquisition in 2017
Mammalian facilities enhanced in 2018

Synthetic pharmaceuticals
Biopharmaceuticals
Synthetic pharmaceuticals and Biopharmaceuticals
# Business locations

<table>
<thead>
<tr>
<th>Company name</th>
<th>base</th>
<th>business</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGC</td>
<td>Chiba, Japan</td>
<td>Synthetic, Bio</td>
</tr>
<tr>
<td></td>
<td>Yokohama, Japan</td>
<td>Synthetic, Bio</td>
</tr>
<tr>
<td>AGC Wakasa Chemicals</td>
<td>Fukui, Japan</td>
<td>Synthetic</td>
</tr>
<tr>
<td>AGC Biologics</td>
<td>Seattle, US</td>
<td>Bio</td>
</tr>
<tr>
<td></td>
<td>Berkeley, US</td>
<td>Bio</td>
</tr>
<tr>
<td></td>
<td>Copenhagen, Denmark</td>
<td>Bio</td>
</tr>
<tr>
<td></td>
<td>Heidelberg, Germany</td>
<td>Bio</td>
</tr>
<tr>
<td>Malgrat Pharma Chemicals</td>
<td>Catalonia, Spain</td>
<td>Synthetic</td>
</tr>
</tbody>
</table>
4. Requirements for CDMOs and AGC’s efforts
Requirements for CDMOs

1. Track record of commercial drug manufacturing
2. Production system fit for customers’ needs
3. Technical competence

Capabilities to provide innovative proposals & Speed
Highly experienced CDMOs are chosen to fulfill the requirements for providing stable quality and the necessary technology.

<Track record of inspection at AGC’s business locations>  
(*including non-commercial drugs)

<table>
<thead>
<tr>
<th>Synthetic pharmaceuticals</th>
<th>AGC (Chiba, Japan)</th>
<th>FDA Food and Drug Administration</th>
<th>EMA European Medicines Agency</th>
<th>PMDA Pharmaceuticals and Medical Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malgrat Pharma Chemicals (Catalonia, Spain)</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bio pharmaceuticals</th>
<th>AGC Biologics (Seattle, US)</th>
<th>FDA Food and Drug Administration</th>
<th>EMA European Medicines Agency</th>
<th>PMDA Pharmaceuticals and Medical Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGC Biologics (Copenhagen, Denmark)</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td></td>
</tr>
<tr>
<td>AGC Biologics (Heidelberg, Germany)</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td></td>
</tr>
<tr>
<td>AGC (Chiba, Japan)</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td></td>
</tr>
</tbody>
</table>
(2) Production system fit for customers’ needs

a. Individualized medicine

**Traditional** pharmaceuticals: Mass/single-item production of low-response-rate drugs

- Heterogeneous patient population
- Determination of the drug to be administered
- Low response rate

The drug to be administered is determined by “rough” diagnosis based on the affected site and symptoms

**Future** pharmaceuticals: Small-scale/multi-item production of high-response-rate drugs

- Heterogeneous patient population
- Detection of biomarkers
- Segmentation of patients
- Determination of the drug to be administered
- High response rate

*Biomarkers: Numerical/quantitative measures of biological information used to quantitatively evaluate biological changes*
## (2) Production system fit for customers’ needs

### b. Enhanced efforts to meet unmet medical needs

Medical needs for diseases for which no effective treatment/cure have been identified

<table>
<thead>
<tr>
<th>Area where there is a “standard care”</th>
<th>“Unmet medical needs” area</th>
</tr>
</thead>
<tbody>
<tr>
<td>A category of treatments considered to be the best treatment currently available based on scientific evidence and recommended for a group of patients with a certain condition.</td>
<td>Medical needs for diseases for which no effective treatment/cure has been identified. These diseases include those affecting a large number of patients for which treatments are highly demanded, and <strong>those affecting a limited number patients for which treatments/cures are still highly demanded.</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Satisfaction with current treatment</th>
<th>High</th>
<th>Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contribution of existing drugs</td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td>Examples of target diseases</td>
<td>Hypertension, tuberculosis, allergic rhinitis, chronic hepatitis, angina pectoris</td>
<td>Cancer, Alzheimer’s disease, Parkinson’s disease, chronic kidney failure, autoimmune diseases, <strong>rare diseases (orphan)</strong></td>
</tr>
</tbody>
</table>
c. Growth of the orphan drug market

- The CAGR of global prescription drug sales between 2018-2024 is estimated to be +6.4% ($830bn in 2018 → $1,204bn in 2024)
- The orphan drug market is expected to show prominent growth. From a technology standpoint, biopharmaceuticals are expected to lead the market's growth.

<table>
<thead>
<tr>
<th></th>
<th>Synthetic pharmaceuticals</th>
<th>Biopharmaceuticals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>New synthetic pharmaceuticals</td>
<td>New biopharmaceuticals</td>
</tr>
<tr>
<td></td>
<td>Sales($bn)</td>
<td>CAGR</td>
</tr>
<tr>
<td>Originals</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orphan</td>
<td>101</td>
<td>2018</td>
</tr>
<tr>
<td>Non-orphan</td>
<td>444</td>
<td>2018</td>
</tr>
<tr>
<td>Total</td>
<td>545</td>
<td>2018</td>
</tr>
<tr>
<td>Generics</td>
<td>Sales($bn)</td>
<td>CAGR</td>
</tr>
<tr>
<td>Non-orphan</td>
<td>61</td>
<td>2018</td>
</tr>
<tr>
<td>Biosimilars</td>
<td>Sales($bn)</td>
<td>CAGR</td>
</tr>
<tr>
<td>Non-orphan</td>
<td>23</td>
<td>2018</td>
</tr>
</tbody>
</table>

AGC Biologics has the capacity and flexibility fit for small-scale/multi-item manufacturing needs

Source: Values estimated by AGC based on data from EvaluatePharma® World Preview 2018, Outlook to 2024
Future developments

Future areas requiring stable and efficient manufacturing methods

- Ex vivo gene therapies (e.g. CAR-T)
- In vivo gene therapies (viral and non-viral)
- Regenerative medicine (e.g. IPS cells)
- Microbiome
- Next-generation antibodies (e.g. antibody fragments, ADC, multivalent antibody, Fc-fusion protein)

Productivity-centered technological development

- Antibodies/Recombinant proteins
- Stem cell drugs (e.g. MSCs, HSCs)

Novel technologies

- Synthetic pharmaceutical drugs
  - Areas of diseases for which certain standard treatments are available

Established technologies

- Area of unmet medical needs
- Orphan drugs etc.

Synthetic pharmaceutical drugs
Sales target towards “Vision 2025”

Sales target for Life Science

<table>
<thead>
<tr>
<th>FY2020</th>
<th>FY2025</th>
</tr>
</thead>
<tbody>
<tr>
<td>65 bn yen or more</td>
<td>100 bn yen or more</td>
</tr>
</tbody>
</table>

M&As, facility expansions

- **2016**
  - Acquired Biomeva (Heidelberg)

- **2017**
  - Acquired CMC Biologics (Copenhagen・Seattle・Berkley)

- **2018**
  - Expanded mammalian capacity in Denmark
  - Expanded mammalian capacity in Berkley

- **2019**
  - Acquired Malgrat Pharma Chemicals
  - Expanded capacity of synthetic in AGC Chiba (starting in FY2019)
  - New construction of mammalian facility in AGC Chiba (starting in FY2019)

- **2020**
  - Expanded mammalian capacity in Seattle (starting in FY2020)
  - Expanded microbial capacity in Seattle (starting in FY2020)

FY2017: 36.7 bn yen
FY18: 44.9 bn yen
FY19e: 55.0 bn yen
FY20e: 65.0 bn yen
FY2025e: 100.0 bn yen
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