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Bio CDMO Business

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Table of Contents

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Positioning of bio CDMO business at FUJIFILM

Strong growth of healthcare as a core business

Life science business

Prevention

Cosmetics
Dietary supplements

Medical systems business

Diagnosis

Diagnostic imaging systems,
Medical IT, Endoscope,
In-Vitro Diagnosis (IVD),
Ultrasound systems

Pharmaceuticals, bio CDMO and regenerative medicine business

Treatment

Bio CDMO*,
Regenerative medicine,
Cell culture media,

Biology

Pharmaceuticals,
Small-molecule CDMO*

The healthcare field is FUJIFILM's main growth pillar in its mid- to long-term management strategy, with the bio CDMO business positioned as a driver for future business growth.

*CDMO: Contract Development & Manufacturing Organization.

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Biopharmaceutical category initiatives

Bio CDMO

Contract Development and Manufacturing of the Bio-pharmaceutical Production Process

FUJIFILM Diosynth Biotechnologies (FDB)

Cell Culture Media

- FUJIFILM Wako Pure Chemical Corporation
- FUJIFILM Irvine Scientific Inc. (FISI)

Bio Science & Engineering Laboratory

Regenerative Medicine

iPS Cells

FUJIFILM Cellular Dynamics Inc. (FCDI)

Somatic Stem Cells

Japan Tissue Engineering Corporation (J-TEC)

Expanding in the biomedical business sector through investment in Bio CDMO, regenerative medicine and cell culture media

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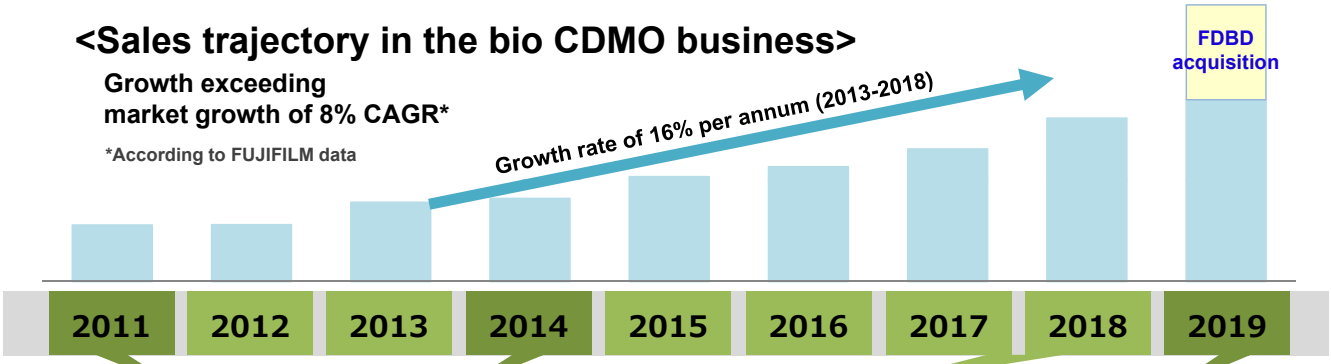
Entry into and subsequent expansion in bio CDMO business

<Sales trajectory in the bio CDMO business>

Growth exceeding market growth of 8% CAGR*

*According to FUJIFILM data



M&A

MSD Biologics/ Diosynth (Today's FUJIFILM Diosynth Biotechnologies)

✓Entry into biopharmaceutical field, which has high growth potential

M&A

Kalon Biotherapeutics (Today's FUJIFILM Diosynth Biotechnologies)

✓Expanding into the bio CDMO business
✓Handling vaccine production

Capital investments

Capital investments worth over 30 billion yen in cumulative total

<Main investments>
FDBT (Texas, USA)
✓cGMP-compliant production facility (operational since FY17)
✓2000ℓ bioreactors x 6 (operational sequentially since FY17)
FDBK (UK)
✓Expansion of a production process development facility and introduction of cutting-edge facilities (operational since FY17)

M&A

Biogen (Denmark) Manufacturing (FDBD: Acquisition completed in August)

✓Addressing large-scale manufacturing needs
✓Accelerating business growth further

Entered the bio CDMO industry in its infancy through business acquisition and expanded business through proactive investments and capability reinforcement in anticipation of market growth

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Global footprint of Bio CDMO Business

FUJIFILM Diosynth Biotechnologies, Billingham, England (FDBK) Acquired in 2011

Biogen (Denmark) Manufacturing Hillerod, Denmark (FDBD) Acquired in 2019

FUJIFILM Diosynth Biotechnologies, North Carolina, USA (FDBU) Acquired in 2011

FUJIFILM
FUJIFILM HQ
Tokyo, Japan

[Collaboration]

Merck & Co., Inc.
Brinny Manufacturing Plant
Cork, Ireland

FUJIFILM Diosynth Biotechnologies, Texas, USA (FDBT) Acquired in 2014

Enhanced process development and manufacturing facilities that support a global client base from clinical journey through to commercialization

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Table of Contents

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Background of growth in the bio CDMO market

◆Increase of biopharmaceuticals in the pharmaceutical market

The biopharmaceuticals segment has continued its growth at the CAGR rate of approx. 8% (worth approx. 27 trillion yen in 2018), due to their advanced efficacy on intractable diseases and limited side effects.

◆Increase of contract development and manufacturing for biopharmaceuticals

Manufacturing drug substances for biopharmaceuticals requires advanced manufacturing / quality control technology, large-scale manufacturing facilities and accumulated know-how, causing an increase of process development and manufacturing contracted to CDMOs.

The bio CDMO market is expected to maintain strong growth, outstripping the growth of biopharmaceuticals as a whole.
(Market size in 2018: Approx. 500 billion yen*)

*Excluding gene therapeutics

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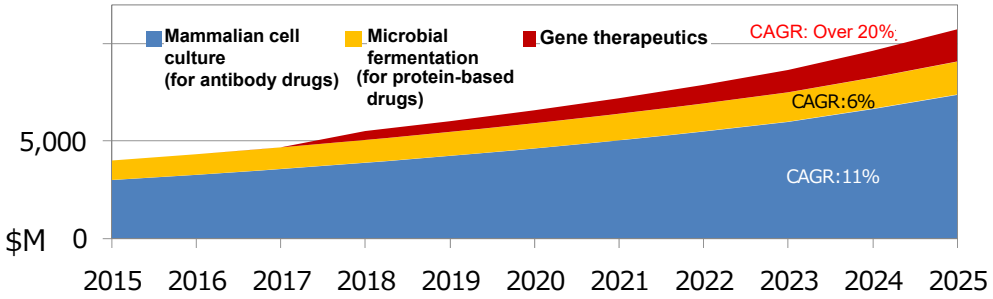
Bio CDMO market trends

1) Manufacturing of drug substances for innovative drugs:
The finer breakdown in the scope of pharmaceutical indications has caused a market shift from low-mix high-volume production to high-mix low-volume production. At the same time, the spread of biosimilars in the market is steadily increasing the need for large-scale manufacturing.

2) Culture methods in the manufacturing of drug substances:
With the expansion of demand for antibody drugs, mammalian cell culture is becoming increasingly popular, although the demand is expanding for both microbial fermentation and mammalian cell cultures.

3) Advanced therapy fields:
The fields of GT (gene therapy) and CT (cell therapy) are rapidly expanding alongside existing market segments including antibody drugs. (GT segment growing at 20% CAGR)

<CDMO API manufacturing market> *FUJIFILM data



Expanding demand in all production volumes, culture methods and pharmaceutical ingredients

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Table of Contents

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Strength of FUJIFILM's bio CDMO business

(1) Culture System

- **Industry-leading mammalian cell expression** technology
- **Industry's highest level** microbial expression technology
- **Advanced culture technology** for human cells used in gene therapy
- Use of **culture medium manufacturer** within the Group

(2) Advanced and diverse manufacturing facilities

- **Mobile clean room** with the world's highest level of containment capability
- State of the art process developing equipment and **industry's shortest development period**
- **Single-use bioreactors** with outstanding flexibility
- **Catering to large-scale manufacturing** through the acquisition of large bioreactors

Single-use bioreactor

(3) Advanced technologies nurtured by FUJIFILM

e.g. manufacturing and quality control technologies to maintain constant product quality under fixed production conditions

FUJIFILM's strength are industry-leading culture system, advanced facilities as well as advanced manufacturing / analysis / engineering technologies nurtured through the photographic film business, and the ability to merge them

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Strength (1) Industry-leading advanced culture technology

- **Industry-leading** mammalian cell expression technology*: "Apollo™X" (over 10g/ℓ)
- **Industry's highest-level** microbial expression technology: "pAVEway™"
- **Advanced culture technology** for human cells used in gene therapy: Utilizing advanced culture technology of FUJIFILM's Bio Science & Engineering Laboratory and FDB's advanced manufacturing facilities
- Use of **culture medium manufacturer** within the Group (FUJIFILM Irvine Scientific): Using original culture medium to optimize culturing conditions

*In the bio CDMO industry (according to FUJIFILM data)

Industry's highest-level in diversity and titer of culturing technologies, including those in the field of advanced medicine
Using original culture medium to ensure optimum culturing conditions

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Strength (2)-1 Advanced facilities

- **Mobile clean room** with the world's highest level of containment capability:
  Conforming to Biosafety Level 3
  World's highest-level mobile clean room as a commercial production facility, manufacturing gene therapeutics and antiviral drugs

Mobile clean room

- State of the art process developing equipment and **industry's shortest development period**:
  The introduction of state of the art equipment and the use of ApolloX for productivity improvement have resulted in the contract development period of 34 weeks, the industry's shortest*, in process development for antibody drugs

*In the bio CDMO industry (according to FUJIFILM data)

Catering to the expanding market needs for contract manufacturing in the field of advanced medicine, including gene therapeutics
Achieving the industry's shortest process development period for antibody drugs to contribute to further reduction in pharmaceutical companies' development and manufacturing cycle

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Strength (2)-2
Diverse manufacturing facilities to meet client needs

Acquisition of FDBD has made it possible to address diverse client needs.

		Base	Description
Three original FDB sites	FDBK	UK Billingham	・Has strength in process development service and microbial fermentation ・Expanded a developing site in 2017
	FDBU	USA North Carolina	・Has strong track record of small-mid scale in GMP grade manufacturing for clinical and commercial products ・Expanding medium-scale manufacturing capacity for antibody and hormone drugs
	FDBT	USA Texas	・Expanding the medium-scale manufacturing capacity for antibody drugs (single-use bioreactors) ・Using a mobile clean room for manufacturing gene therapeutics and vaccines ・Adding a new fill/finish line
After Aug. 2019 acquisition	FDBD	Denmark Hillerød	・6 x 15,000L large bioreactors ・Enabling large-scale manufacturing to meet wider client needs

Meeting diverse client needs, ranging from microbial fermentation, mammalian cell culture, gene therapeutics to vaccines, from clinical to commercial products, from process development service to manufacturing drug substances, from small- to large-scale manufacturing

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Strength (3) Advanced technologies nurtured by FUJIFILM

FF technologies refined through various products including photographic films	Applications to bio CDMO business
Highly-reliable and high-quality production technologies ・Constant-condition manufacturing / quality control technology ・Highly-reliable, high-quality and low-cost production technology (engineering technology)	・Stabilizing and streamlining production processes （20% success rate improvement following FDB acquisition） ・Automatic control technology
Analysis technology	・Providing analysis services ・Developing advanced analysis technology
Design and process development capability	・Clearing technical hurdles, cost reduction to streamline processes ・Own advanced facility design （Equipment for continuous culture and refining process development）
Imaging technology	・FUJIFILM's own fast and affordable gene analysis technology using chromogenic method

Applying FUJIFILM's diverse collection of advanced technologies to biopharmaceutical business to substantially streamline production / process development

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Table of Contents

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Industry trends and FUJIFILM's growth strategy

Industry trends		FUJIFILM's growth strategy
(1) Developing high-productivity technology	⇒	Developing the industry's first* fully integrated continuous production system *In the bio CDMO industry (according to FUJIFILM data)
(2) Offering one-stop services	⇒	Adding new fill/finish lines
(3) Expanding into the field of advanced medicine	⇒	Investing in the field of gene therapy

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Trend (1) Developing high-productivity technology

・The bio CDMO market is expected to achieve growth mainly in small- to medium-scale drugs, while the demand for large-scale drugs is also forecast to make a steady increase. In expanding production capacity, flexible manufacturing facilities must be introduced to cater to different production scales.
⇒ Active technological development of a continuous production method, which is more flexible and has higher investment efficiency than the conventional batch-production method

FUJIFILM has become the first in the bio CDMO industry* to develop an **innovative, fully-integrated continuous-production system, seamlessly connecting all processes from upstream to downstream**.
The system is due to start contract process development this fiscal year and launch commercial operation of a 500L bioreactor in 2022.
This enables controlling production volume by the number of operational days.
Original culture medium optimized for continuous production has also been jointly developed with FISI.
*** FUJIFILM data)**

Leveraging the Group's comprehensive capability (production conditions / quality control / engineering technology and culture medium development capacity) to develop continuous production technology, thereby enabling high-quality and high-efficiency production of active pharmaceutical ingredients

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Trend (2) Offering one-stop services

- Increase in contract development and manufacturing in biopharmaceuticals lead to expanding client needs for one-stop services covering process development, manufacturing of drug substances and drug products. This reduces transportation risks on drug substances for expensive biopharmaceuticals and lower workload in relation to obtaining permit / licenses.

FUJIFILM is building a new fill/finish line at FDBT (Texas site), which is due to go operational in 2021.

One-Site, One-Stop CDMO

Process development

API manufacturing

Fill/Finish

Expanding one-stop services to meet further client needs

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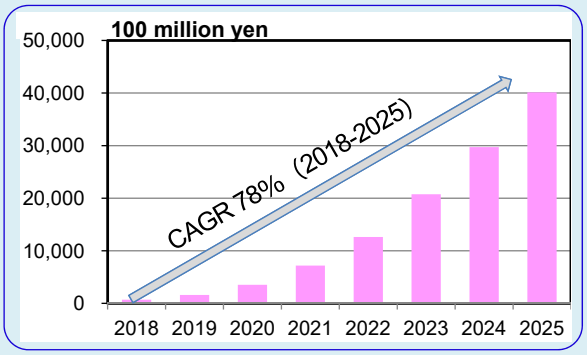
Trend (3) Expanding into the field of advanced medicine

- In the field of advanced medicine, R&D for gene therapeutics is becoming active as they have the potential to fundamentally treat medical conditions. Their market scale is predicted to grow rapidly.
- The manufacturing of gene therapeutics requires advanced biotechnologies and virus-containing technologies / facilities, which heightens market needs to outsource their process development and manufacturing integrally to CDMOs.

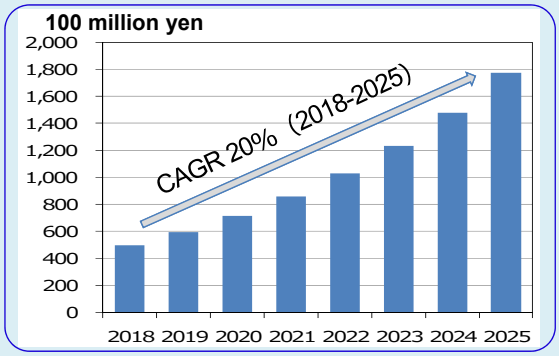
<Market prediction for gene therapeutics>
***Commercial use only** ***FUJIFILM data**

70 billion yen in 2018 → 4 trillion yen in 2025



<Market prediction for gene therapeutic CDMOs>
***For investigational drugs & commercial use** ***FUJIFILM data**

50 billion yen in 2018 → 180 billion yen in 2025



***Many gene therapeutics are currently developed by ventures and academia, who heavily rely on CDMOs due to the difficulty in directly handling viruses.**

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Trend (3) Expanding into the field of advanced medicine

Capital investment totaling 13 billion yen to expand gene therapy capabilities

- Adding process development and manufacturing facilities at FDBT (Texas site), which has the world's highest-level containment technology and facilities to meet market needs for gene therapeutic CDMO
- Using FDB's cells, genes and original culture medium to provide optimum production processes swiftly
- Developing a production line for manufacturing clinical and commercial products to meet client needs

Investment details		Construction to start in	Operation to start in
Process development	・Constructing a new building ・Introducing culturing, refining and analyzing equipment	December 2019	Autumn 2021
Manufacturing facilities	・Adding new clean rooms ・Installing eight new bioreactors (500L/2,000L)	December 2019	Sequentially from spring 2021

Expanding development and manufacturing facilities for gene therapeutics, whose market is expanding rapidly
Tapping into FUJIFILM's strength to accept integrated contract covering production process development to manufacturing and accelerating business expansion in the field of advanced medicine

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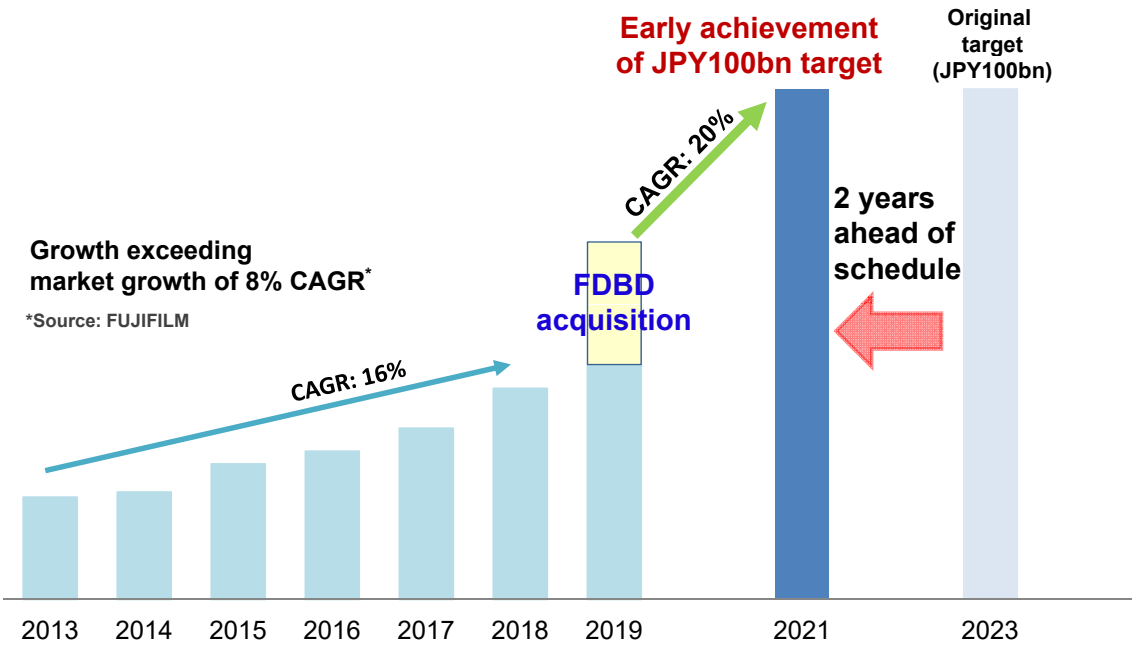
Target of bio CDMO business



Leveraging solid technological and manufacturing foundation to further accelerate growth and meet the revenue target of JPY100bn by FY2021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