



# The Growth Strategy of FUJIFILM through the acquisition of a biopharmaceutical manufacturing company

FUJIFILM Holdings Corporation
Chairman and CEO
Shigetaka Komori
March 12, 2019





#### Fujifilm "NEVER STOP" Evolving

# To become "a company driving changes" for a continuous growth

### Adapt to changes

In the 2000s

Drastically transformed business structure to adapt to the rapid

decrease of color film demand

# Predict changes and take initiatives

Predict market and invest in business incl. M&As

#### **Drive changes**

Lead market by creating new values with numberone and proprietary technologies

Continue timely and decisive management to keep on creating new products and value





**Biology** 

#### Medium-Term Management Plan "VISION2019"

#### Strong growth of healthcare as a core business

#### Prevention

**Cosmetics Dietary supplements** 

#### **Diagnosis**

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





#### **Treatment**

Bio CDMO\*1, Regenerative Medicine, Cell Culture Media, Pharmaceuticals, Small-molecule CDMO\*1



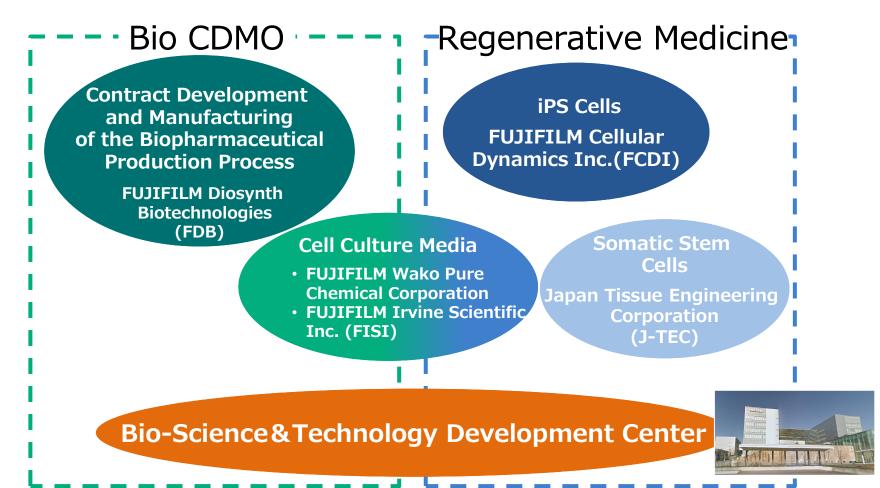
 Actively expand the medical biology field such as bio CDMO and regenerative medicine





#### Biopharmaceutical category initiatives

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







#### **Growing Bio CDMO market**

#### ◆ Biopharmaceutical market

Biopharmaceutical market is expected to continue to grow with 8% annually due to higher efficacy for intractable diseases and rare diseases with lesser side effect

(Market size: approximately JPY27trillion in 2018)



#### ◆Bio CDMO market

- Manufacturing biologics requires high quality control technologies, large-scale manufacturing facilities, and accumulated know-how which are large barrier to entry.
- Outsourcing of process development and manufacturing to CDMO with highly-skilled capabilities and expertise is increasing
- Fujifilm focuses on BioCDMO, expected to grow beyond the growth of biopharmaceuticals, and invest management resources.





### Significance of acquiring a biopharmaceutical manufacturing company

Acquisition of Denmark manufacturing subsidiary from Biogen Inc, a leading global biopharmaceutical company, for approximately USD890mm\*1

This acquisition is expected to be completed around August 2019

- <Expected achievements>
- > Through addition of large scale bioreactors
  - 1. Enhanced production capabilities
  - 2. Provide comprehensive manufacturing solutions covering smalllarge production demands
- Expansion of business in the medical biology sector through creating collective synergy by deployment of group resources such as cell culture media and cell-related technologies

Through supporting the acceleration of biopharmaceutical development, and contributing to the growing healthcare industry, Fujifilm, resolves to address social issues for unmet medical needs





# Acquisition of a Biogen's Manufacturing Company in Denmark and the Growth Strategy of Fujifilm's CDMO business

FUJIFILM Holdings Corporation
President and COO
Kenji Sukeno
March 12, 2019





#### Overview of Biogen Inc.

Company name : Biogen Inc.



One of the world's leading biopharmaceutical companies

Headquarter : Cambridge, Massachusetts, United States

Established : 1978

Overview : ·Has its strength in Central nervous system,

rare disease, and neurodegenerative disease

·Has introduced treatment for multiple sclerosis

and spinal muscular atrophy

Financial result : Revenue: USD13.5bn

Operating profit: USD5.9bn

(Consolidated, FY2018)

CEO : Michel Vounatsos

Manufacturing site: Denmark, US, Switzerland(building)





#### **Overview of Biogen's Manufacturing Subsidiary in Denmark**

Company name : Biogen (Denmark) Manufacturing ApS

Location : Denmark Hillerod (purlieus of Copenhagen)

Established : 2003

Business : • Multi-product manufacturing facility delivering

marketed therapeutics including multiple sclerosis

·Large scale biologics manufacturing, labeling and

packaging, quality laboratories and contract

research all supported by its high-end

biotechnology and manufacturing know-how

<Detail>

Manufacturing Capacity

: 90,000L

 $(15,000L\times6 \text{ reactors})$ 

No. of employees : Approximately 800

Building area : 48,000m<sup>2</sup>

(8 building blocks)

Site area : 247,000m<sup>2</sup>







#### **Global footprint of our Bio CDMO Business**

- •Enhanced manufacturing facilities that support a global client base throughout the clinical journey through to commercialization
- ·Our 4th Bio CDMO site will be added through this acquisition

#### **FUJIFILM**

Diosynth Biotechnologies, Billingham, England

Acquired 2011



Biogen (Denmark) Manufacturing Hillerod, Denmark



FUJIFILM
Diosynth Biotechnologies,
North Carolina, USA
Acquired 2011



FUJIFILM HQ Tokyo, Japan

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[Collaboration]

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



FUJIFILM
Diosynth Biotechnologies,
Texas, USA
Acquired 2014





#### Overview of our Bio CDMO manufacturing base

Fujifilm Diosynth Biotech -nologies Group	Base	Geography	Overview
	FDBK*1	Billingham England	<ul> <li>Has strength in process development service</li> <li>Expanded developing site in 2017</li> </ul>
	FDBU*1	North Carolina USA	·Has strong track record of small-mid scale GMP*2 grade manufacturing for clinical and commercial products
			•Expanding mid-scale manufacturing capacity for biologics production
	FDBT*1	Texas USA .	Expanding mid-scale manufacturing capacity for antibodies
			Has high containment technologies and capability to manufacture advanced therapies
D'a man			·Has six 15 000L large-scale hioreactors

Biogen (Denmark) Manufacturing

Hillerod Denmark

- ·Has six 15,000L large-scale bioreactors
- Adds large-scale manufacturing capability to the FDB Group to meet wider client needs

<sup>\*1</sup> FDBK: FUJIFILM Diosynth Biotechnologies UK Limited (Fujifilm 80%, Mitsubishi 20% share) FDBU: FUJIFILM Diosynth Biotechnologies U.S.A. Inc. (Fujifilm 80%, Mitsubishi 20% share) FDBT: FUJIFILM Diosynth Biotechnologies Texas, LLC (FDBU 100% share)

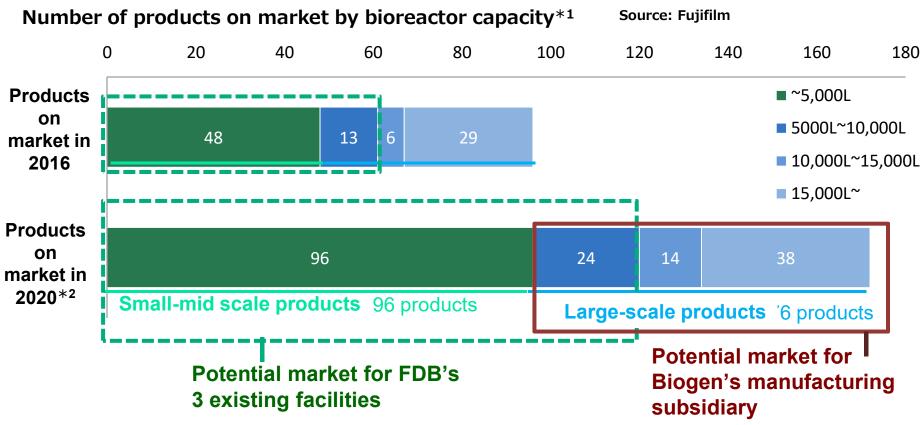
<sup>\*2</sup> GMP refers to the Good Manufacturing Practice Regulations promulgated by the US Food and Drug Administration etc.





#### Strategic significance of this acquisition to our Bio CDMO business (1)

 Provide comprehensive manufacturing solutions covering small to large scale production demands throughout the clinical journey, including commercialization



<sup>\*1.</sup> Optimal bioreactor scale (mammalian expression) based on the assumption of producing once a month and ten batches per year 6

<sup>\*2.</sup> Estimate based on success rate considering number of preclinical pipelines





#### Strategic significance of this acquisition to our Bio CDMO business (2)

 Acquisition of existing manufacturing contracts with Biogen and other major pharmaceuticals and highly-skilled professionals as well as facilities' strong track record

• Situated in a location with sufficient space for <u>capacity</u> <u>expansion</u> to further support the biopharmaceutical industry e.g., drug substance manufacturing, drug product filing







#### Strength of FUJIFILM's Bio CDMO Business

·Our strength is industry-leading expression system, advanced facilities, and technologies coupled with the advanced manufacturing technologies developed through the photographic film business

#### **Expression System**

- Industry-leading microbial and mammalian expression platforms\*1
- Experts in gene therapy production



#### **Advanced facilities**

- State of the art manufacturing solutions small-high volume scale
- High containment mobile cleanroom technologies\*2
- Best in class process development capabilities



Single use bioreactor

Application of Fujifilm's advanced manufacturing technologies to manufacture under constant conditions and superior quality control



Mobile clean rooms

<sup>\*1: &</sup>quot;ApolloX" advanced mammalian expression system is capable of delivering industry leading titres in excess of 10 g/L in Bio CDMO industry based on Fujifilm data as of February 20, 2019

<sup>\*2:</sup> Complies to BSL-2+ (Biosafety Level) containment with capabilities to comply to BSL-3, which is in the top-tier level as a facility for commercial manufacturing





#### Strategy of Bio CDMO business

#### Active investment for expand capability

- Adds large-scale manufacturing capability through this acquisition, total scale of tanks to be  $150,000L^{*1}$ , three times of current scale
- Sales rank will be 2<sup>nd</sup> group from 3<sup>rd</sup> group in bio CDMO industry
   Further enhancement of productivity
- Developed ApolloX mammalian expression system is capable of delivering industry leading\*2 titres in excess of 10 g/L
- Developing next generation technology continuously

#### Fill Finish services to include recombinant protein

Offer full service CDMO from bulk drug substance to fill/finish (2021~)

## Achieving business expansion through providing comprehensive manufacturing solutions

- Antibodies, recombinant proteins, gene therapy and vaccine products
- process development and small-large scale manufacturing
- manufacturing of drug substance to fill/finish

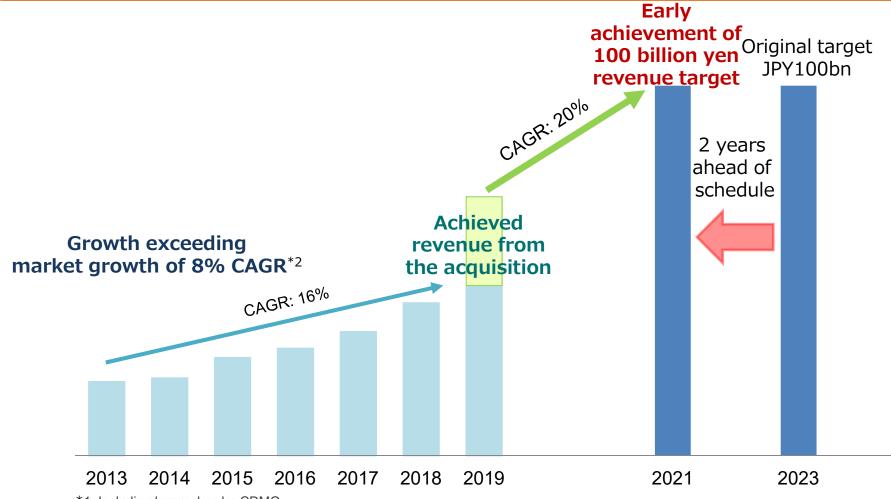
<sup>\*1:</sup> Total of tank size for mammalian cell culture and microbial fermentation, including expanding facilities in-house .

<sup>\*2:</sup> In Bio CDMO industry based on Fujifilm data as of March 12, 2019

#### Bio CDMO revenue target post acquisition



Further acceleration in Bio CDMO business through the acquisition Expected to reach the revenue target of 100 billion yen\*1 in FY2021 ending Mar 2022, 2 years ahead of original schedule



<sup>\*1:</sup> Including low molecular CDMO

<sup>\*2:</sup> Source: FUJIFILM

