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Fujifilm's Bio CDMO Business

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To begin with, let me go through the contents of this presentation, which consists of five portions.

1) Structure and position of the Bio CDMO Business within Fujifilm
2) Outlook for the Bio CDMO market and Fujifilm's business
3) Competitiveness of Fujifilm's bio CDMO business
4) Strategies for further growth
5) Fujifilm’s CDMO activities related to vaccines and therapeutics for COVID-19

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Position of the Bio CDMO Business within Fujifilm

Aim to make the healthcare business our main pillar of growth

Life science business	Medical systems business	Pharmaceuticals, bio CDMO and regenerative medicine businesses
Prevention	Diagnosis	Treatment
Cosmetics Dietary supplements	Diagnostic imaging systems, Medical IT, Endoscope, In-Vitro Diagnosis (IVD), Ultrasound systems	Bio CDMO*, Regenerative medicine, Cell culture media, Pharmaceuticals, Small-molecule CDMO*

Biomedical segment





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

*CDMO: Contract Development & Manufacturing Organization

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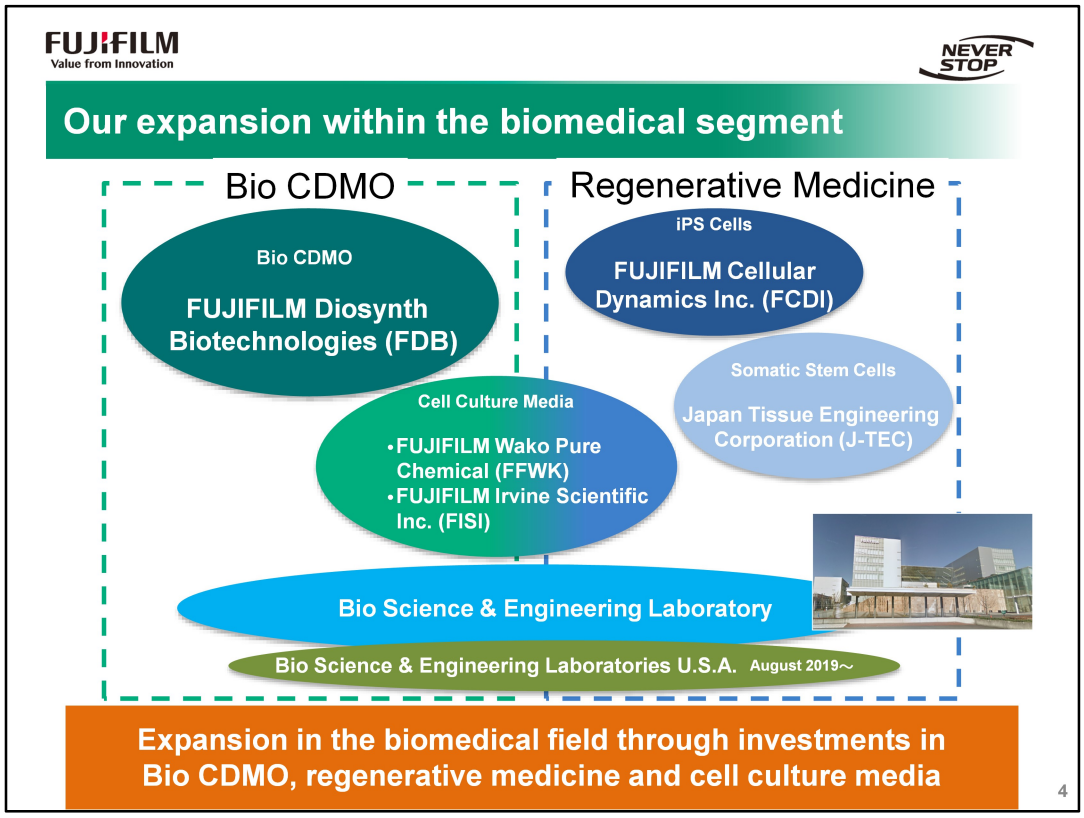
This is how we position the Bio CDMO Business within Fujifilm.

The main message here is that we're aiming to grow the healthcare business as a main pillar within the Fujifilm group in terms of "Prevention", "Diagnosis", and "Treatment" as a mid- to long-term management strategy. Our bio CDMO business is positioned as a strong driver for future growth.

In terms of "Treatment", we are focusing a little more on the area surrounded by the red dotted line, which we refer to in the next slide as the "Biomedical field".



We further divide the "Biomedical segment" into two subcategories: “Bio CDMO” and “Regenerative Medicine”, that describes the activities of several of our subsidiaries globally.

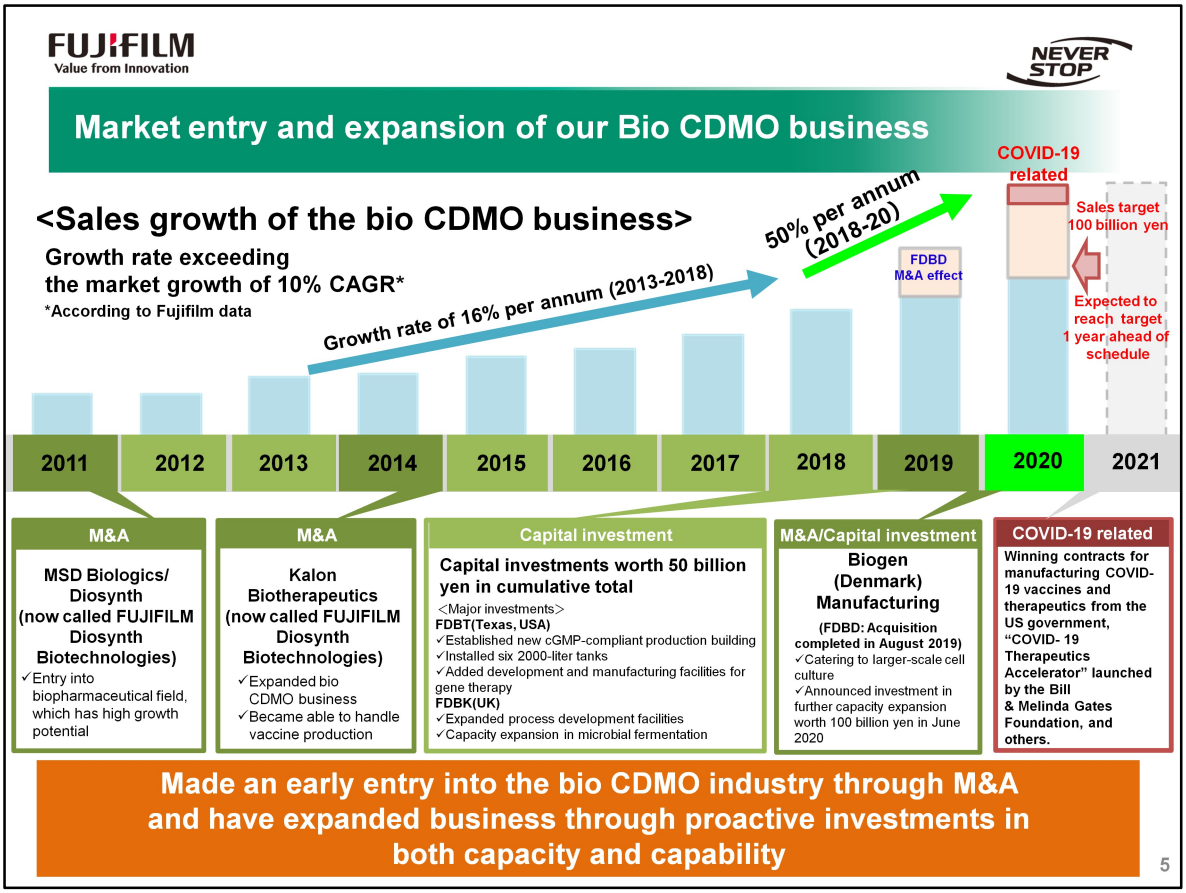
Under the Bio CDMO category, we have FUJIFILM Diosynth Biotechnologies.

In the Regenerative Medicine category, we have FUJIFILM Cellular Dynamics for the iPS cells market, and Japan Tissue Engineering Corporation for somatic stem cells.

Belonging to both categories are FUJIFILM Irvine Scientific and FUJIFILM Wako Pure Chemical which provide cell culture media.

Underpinning corporate R&D activities are Fujifilm’s Bio Science & Engineering Laboratory in Japan and its U.S. branch, which was recently opened.

In this way, we are expanding our position in the biomedical segment through investments into Bio CDMO, regenerative medicine, and cell culture media.



Let's move on to the next topic: how we entered and have expanded the bio CDMO business.

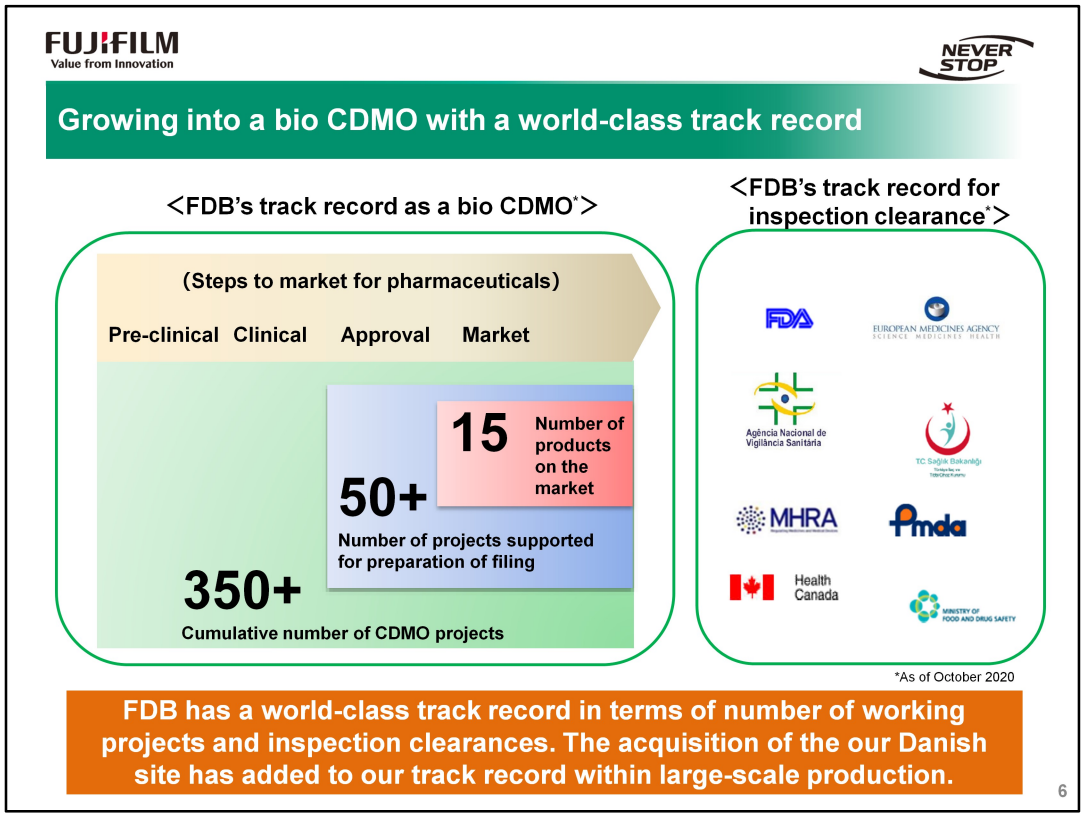
The main message of this slide is that we've grown our bio CDMO business faster than the market.

While in the earlier years between 2013 to 2018 our CAGR was 16%, the acquisition of our facility in Denmark has boosted our growth rate to 50%.

As for this fiscal year, due to the upside potential from COVID-19 related demand, we are now expecting to reach 100 billion-yen in sales, which was originally the target for FY2021.

We entered this business in 2011 by acquiring two biopharmaceutical facilities from Merck, located in North Carolina in the U.S. and Billingham in the U.K., which are now part of FUJIFILM Diosynth Biotechnologies (FDB). In 2014 we further acquired Kalon Biotherapeutics, now called FUJIFILM Diosynth Biotechnologies Texas. What is characteristic about the Texas facility is that it can produce vaccines and gene therapy drugs.

In 2019, we made the most recent and largest acquisition to date when we bought Biogen Denmark Manufacturing. From 2021 onward, COVID-19 related orders will have a positive impact on our business. This includes orders from US government and the "COVID- 19 Therapeutics Accelerator" launched by the Bill & Melinda Gates Foundation, etc.

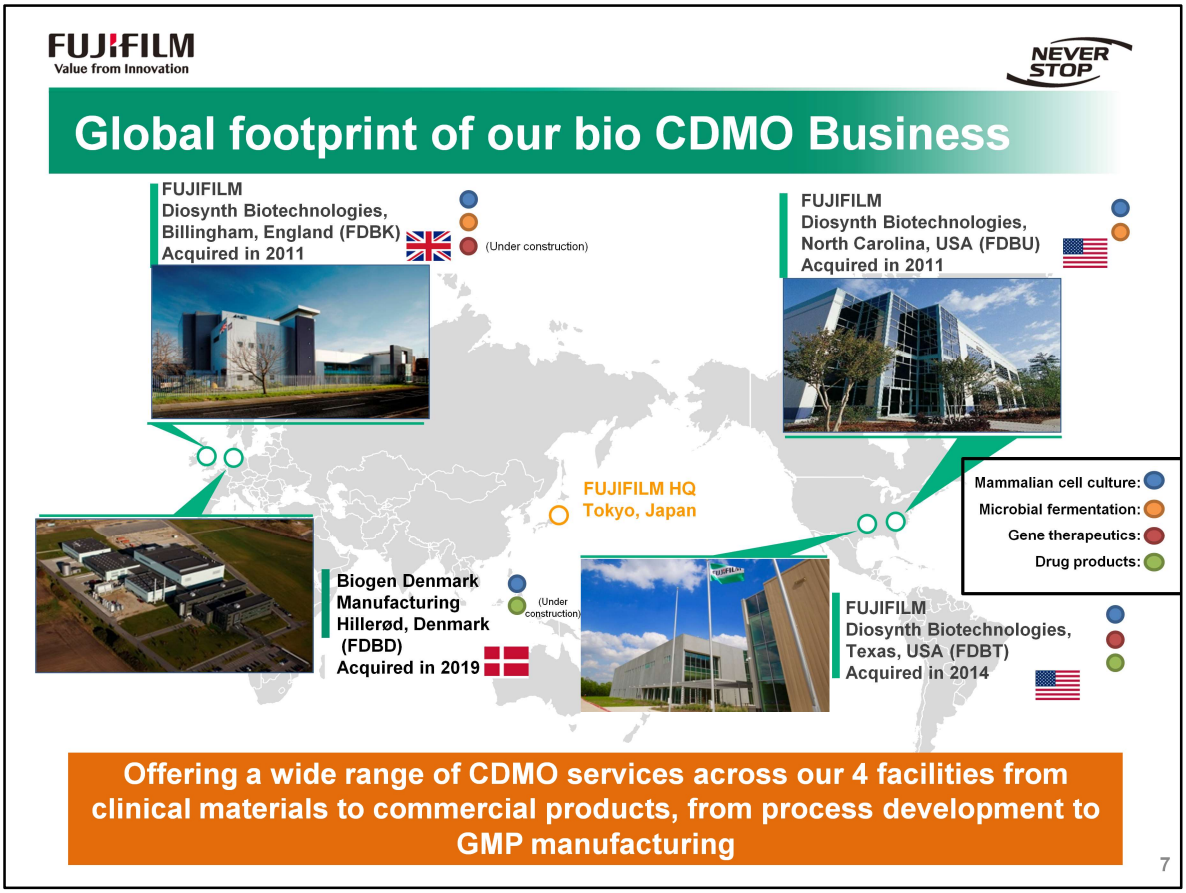


This slide shows the track record of our Bio CDMO.

FDB has a world-class track record in the number of working projects and inspection clearances.

The acquisition of our Danish site has added to our track record within large-scale production.

Figures shown here are the numbers of products on the market and the cumulative number of projects.



This slide shows the global footprint of our Bio CDMO business.

We currently have four facilities globally, two in Europe and the other two in the U.S.

We offer a wide range of CDMO services across our four facilities from clinical materials to commercial products and from process development to GMP manufacturing.

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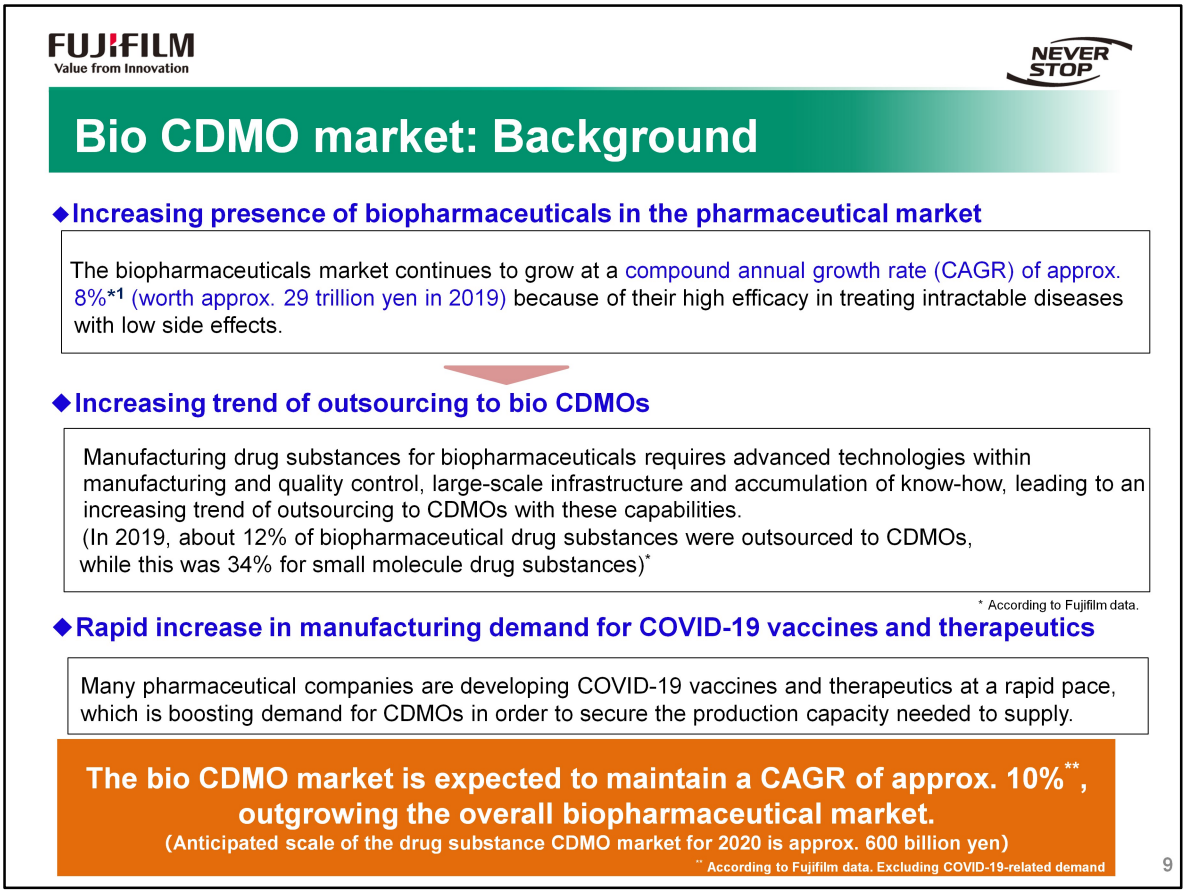
Let me go to the next section: Outlook for the Bio CDMO market and Fujifilm's business.



So, this is how we see the market as background information.

1) Within the pharmaceutical market, there is an increasing presence of biopharmaceuticals which on a worldwide basis currently are worth 29 trillion and growing at a rate of 8% yearly.

2) There is an increasing trend of outsourcing to CDMOs.

In 2019, about 12% of biopharmaceutical drug substances were outsourced to CDMOs, while this was 34% for small molecule drug substances. This means there is further room for biopharmaceutical companies to outsource to CDMOs. We therefore anticipate this ratio of outsourcing will increase for the time being.

3) Finally we're seeing a rapid increase in manufacturing demand for COVID-19 vaccines and therapeutics.

As indicated here, many pharmaceutical companies are busy quickly developing COVID-19 vaccines and therapeutics, which is boosting demand for CDMOs to secure the production capacity needed to supply. In summary, the bio CDMO market is expected to maintain CAGR of approx. 10%, outgrowing the overall biopharmaceutical market.

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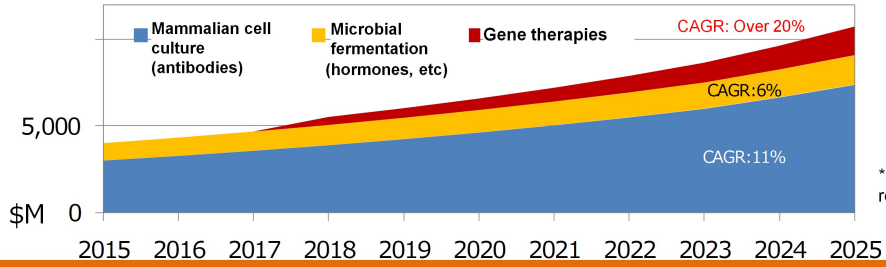
Bio CDMO market: trends

1) **Manufacturing of novel drug substances:** 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 manufacturing drug substances:** With the expansion of demand for antibodies, mammalian cell culture is becoming increasingly popular, while the demand for microbial fermentation is increasing as well.
3) **Advanced therapies:** The demand for GT (gene therapy) drugs and CT (cell therapy) drugs is rapidly increasing alongside conventional drugs such as antibodies. (GT drugs are growing at a CAGR of over 20%)
4) **COVID-19 therapeutics and vaccines:** Manufacturing demand for COVID-19-related pharmaceuticals are, going by the numbers announced by CDMOs so far, worth in excess of 100 billion yen spread over several years (this includes subsidies for manufacturing facilities).

<Bio CDMO market for drug substances*> *Fujifilm data



*Excluding COVID-19-related demand

Overall increase in demand regardless of production volume, culture method and type of biopharmaceutical

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This area chart shows the market size of Bio CDMO by drug substance, based on our knowledge.

The blue area is mammalian cell culture, or in other words “antibody drugs.” It includes the major portion of the Bio CDMO drug substance market, becoming increasingly popular with the growth rate of 11%.

The orange area is microbial fermentation, like hormones, etc. Though the size of this area is smaller, we can say it’s steadily increasing by 6%.

And the 3rd area is the quickly growing segment for gene therapies. The growth rate of this segment is exceeding 20%.

Please note that recent COVID-19 related demands are not included in this graph. So if you are talking about COVID-19 related demand, the manufacturing requests for COVID-19-related pharmaceuticals, as far as revealed by some CDMOs, are worth in excess of 100 billion yen over several years (including financial support for manufacturing facilities). So these additional demands should be taken into consideration to grasp a complete view of the market.

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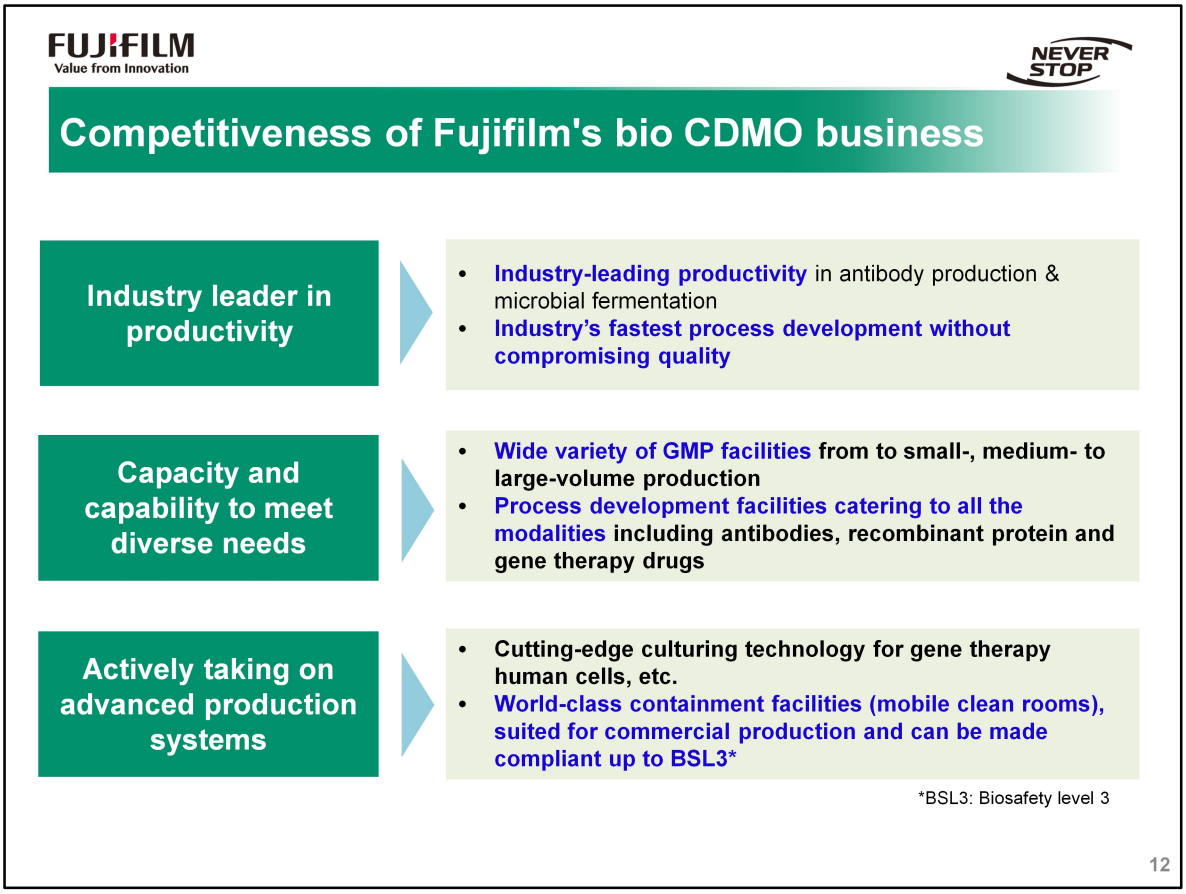
Now, let’s move on to the competitiveness of Fujifilm’s bio CDMO business…

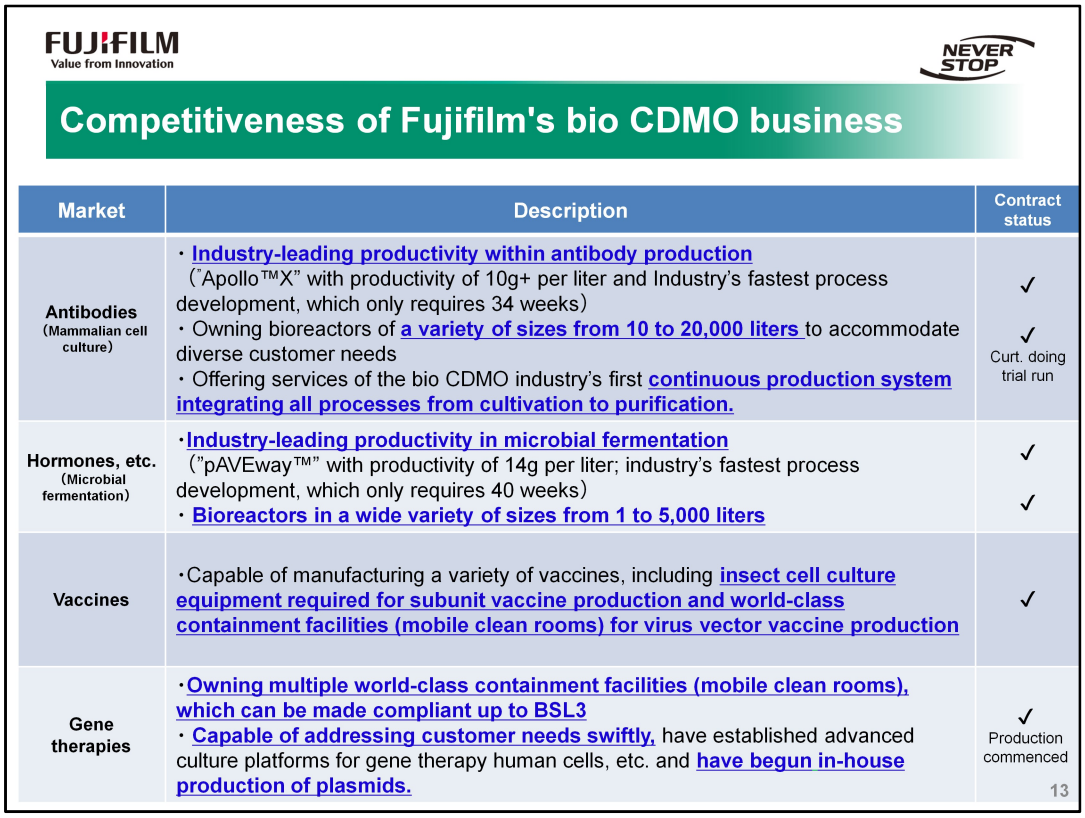


We can summarize our competitiveness into the following three elements:

1) Industry leader in productivity,

2) Capacity and capability to meet diverse needs, and

3) Actively taking on advanced production systems



This slide explains more in detail about our competitiveness seen from the market.

When it comes to antibodies, we have achieved the industry-highest productivity within antibody production by developing our own advanced production technology named “Apollo™ X”, which has realized productivity levels of 10g per liter as well as the industry's fastest process development requiring only 34 weeks. We have bioreactors of a variety of sizes from 10 to 20,000 liters in order to accommodate diverse customer needs. Furthermore, we are offering services using the bio CDMO industry's first continuous production system that integrates all processes from cultivation to purification. We are also industry leaders in productivity for hormones and microbial fermentation. Our unique technology “pAVEway™” has enabled productivity of 14g per liter and the industry's fastest process development requiring only 40 weeks. In addition, we own various sizes of bioreactors from one to 5,000 liters.

In terms of vaccines, we have a variety of manufacturing capabilities, including insect cell culture equipment required for subunit vaccine production and world-class containment facilities, which we refer to as “mobile clean rooms”, for virus vector vaccine production.

As for gene therapy drugs, we own multiple containment facilities that can be made compliant up to BSL (Bio Safety Level) 3, we have established advanced culture platforms for gene therapy human cells, etc. and have also started in-house production of plasmids. This enables us to swiftly address various customer needs.

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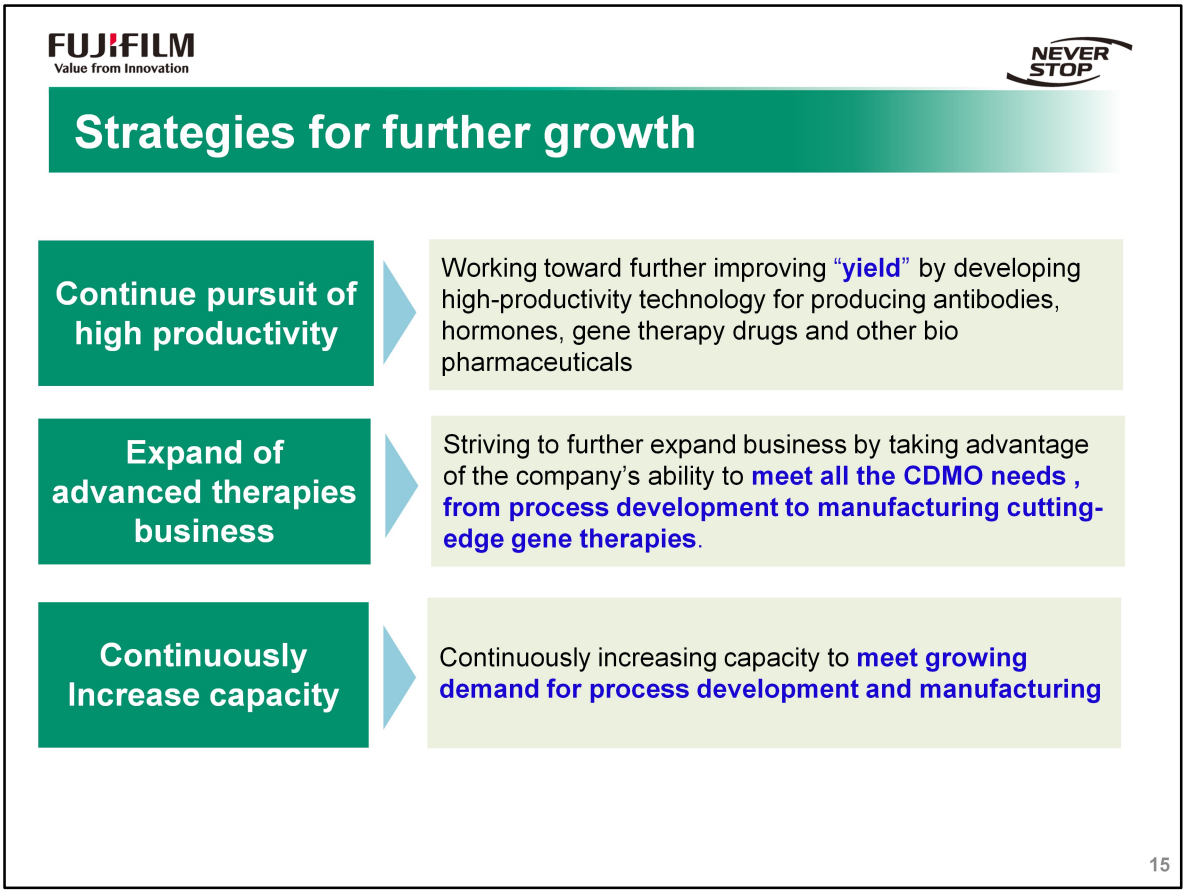
Now, let’s look at Fujifilm’s strategies for further growth…



Our growth strategies can be summarized as the following:

1) Continue pursuit of high productivity,
2) Expand advanced therapies business, and
3) Continuously increase capacity

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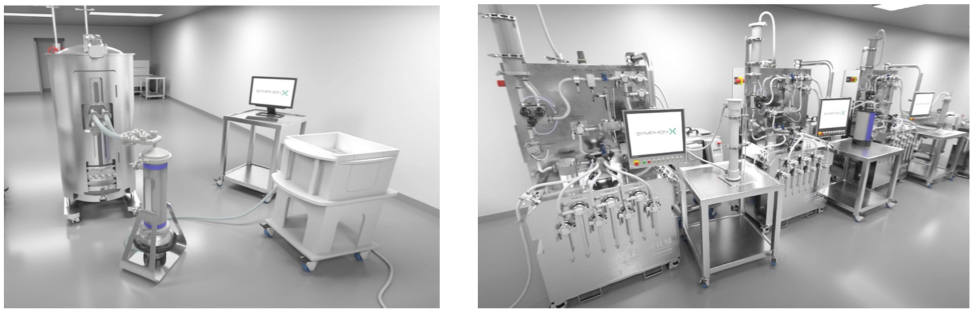
Continue pursuit of high productivity

Fujifilm has developed an **innovative, fully-integrated continuous-production system, seamlessly connecting all processes from culture to purification**, a first in the bio CDMO industry*, and have begun using it for process development services. A 500L bioreactor was installed at the UK site and is currently being tested, manufacturing services to commence in FY2021. The facility can control production volume by changing duration of operation.
Original cell culture media optimized for continuous production has been jointly developed with FISI.

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



Pictures: Continuous Production System

First in the bio CDMO industry to start test operation of a continuous production system
High-quality, high-efficiency drug substance production to meet customer needs

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This slide is about the 1st strategy, which is to continue pursuit for high productivity.

Recently, Fujifilm has developed an innovative, fully-integrated continuous-production system that seamlessly connects all processes from culture to purification. We believe this is the first such achievement in the bio CDMO industry, and we have also already started process development services. Currently a 500L bioreactor installed at the UK facility is being tested, and we expect to start manufacturing services in FY2021. What is characteristic about this facility is that we can control production volume, not by changing the volume of the bioreactor, but simply by changing the duration of operation.

To make this happen, it is very important to prepare cell culture media customized to each pharmaceutical. In this aspect, we are can count on the support of Fujifilm Irvine Scientific Inc., with who we have already developed and optimized cell culture media for the continuous production system.

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Expand advanced therapies business

Total capital investment of 13 billion yen in facilities for process development and manufacturing of gene therapies

- Add facilities for process development and manufacturing at FDBT (Texas site), which has world-class containment facilities, to meet market demand for gene therapy process development and manufacturing
- Use FDB's cells, genes and original cell culture media to swiftly provide optimal production processes
- Develop production lines for manufacturing clinical and commercial products to meet client needs
- Make a capital investment at the U.K. site to underpin gene therapy CDMO business in Europe

Investment details		Start of construction	Start of operation	Location
Facilities for process development & manufacturing	・Construction of a new building for process development ・Installation equipment for process development ・Addition of new clean rooms ・Installation of equipment for manufacturing drug substances	December 2019	Gradually from spring 2021	Texas
	・Installation of equipment for process development ・Installation of equipment for manufacturing drug substances	December 2020	Stepwise commencement from the spring of 2021	Billingham, UK

Capacity expansion for process development and manufacturing aimed at the rapidly growing market for gene therapy. Also, preparation of capabilities for next-generation modalities such as cell therapy, ADCs and bispecific antibodies

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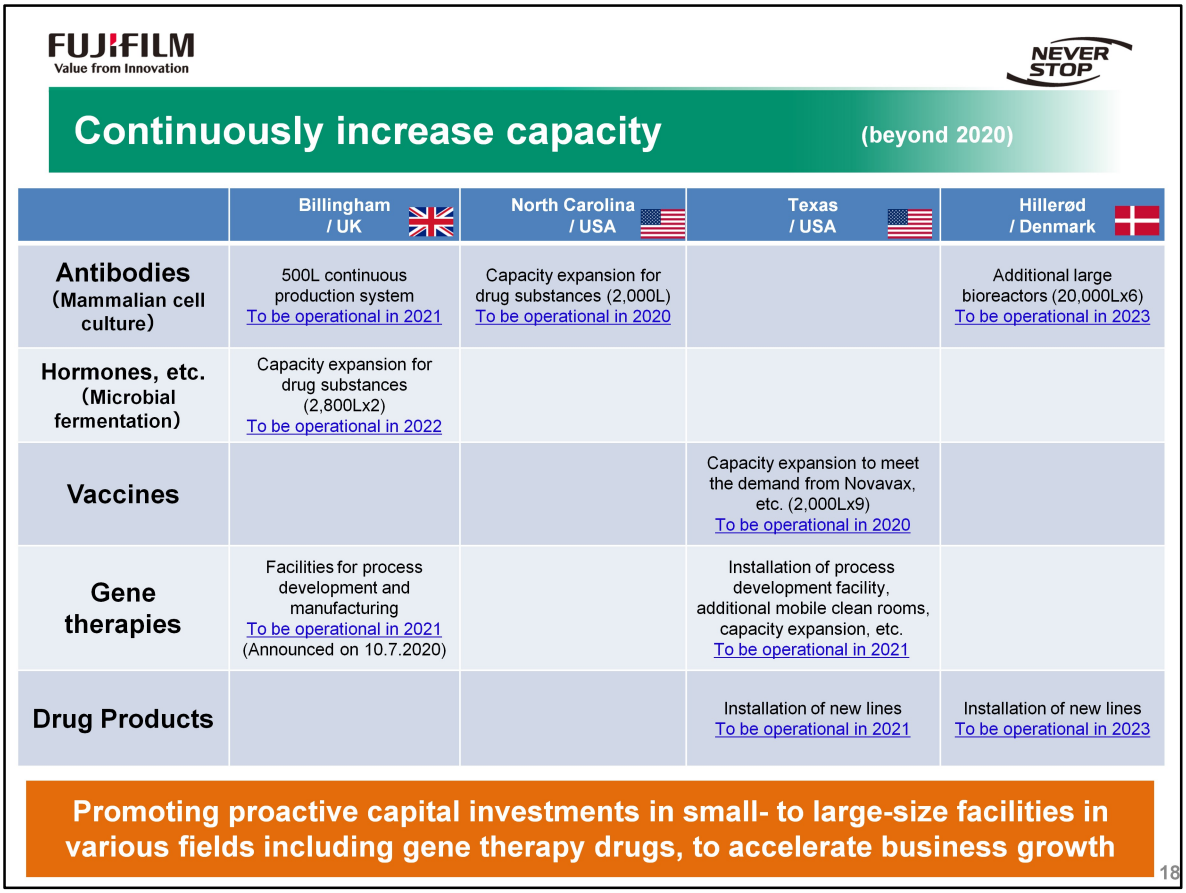
Our 2nd strategy is to expand our advanced therapies business.

We have also been making a capital investment of 13 billion yen in facilities for process development and manufacturing of gene therapies. This investment consists of two parts: One is investments in our Texas site, and the other is in our Billingham site in the U.K.

We will soon be able to offer gene therapy CDMO in both North America and Europe.



This is the overview of our plan for expanding production capacity.

The point here is that we are investing facilities for these five categories. We are proactively making capital investments in small- to large-scale facilities for various modalities, including gene therapy, in order to accelerate business growth.

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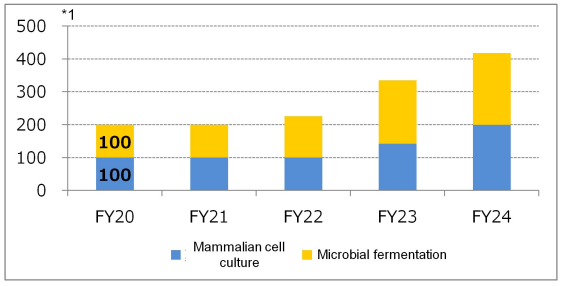
Production capacity expansion plan

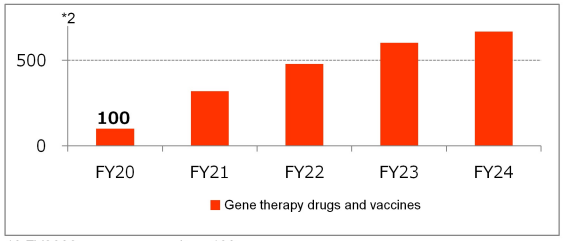


*1 FY2020 annual production capacity = 100

Expansion plan for production capacity of Microbial fermentation / Mammalian cell culture (FY20→FY24)

Microbial fermentation **2.2x**

Mammalian cell culture **2.0x**



*2 FY2020 program capacity = 100

Expansion plan for production capacity of gene therapy drugs and vaccines (FY20→FY24)

Gene therapy and vaccines **6.7x**

Expanding production capacity at a rate outpacing the market in order to achieve drastic growth

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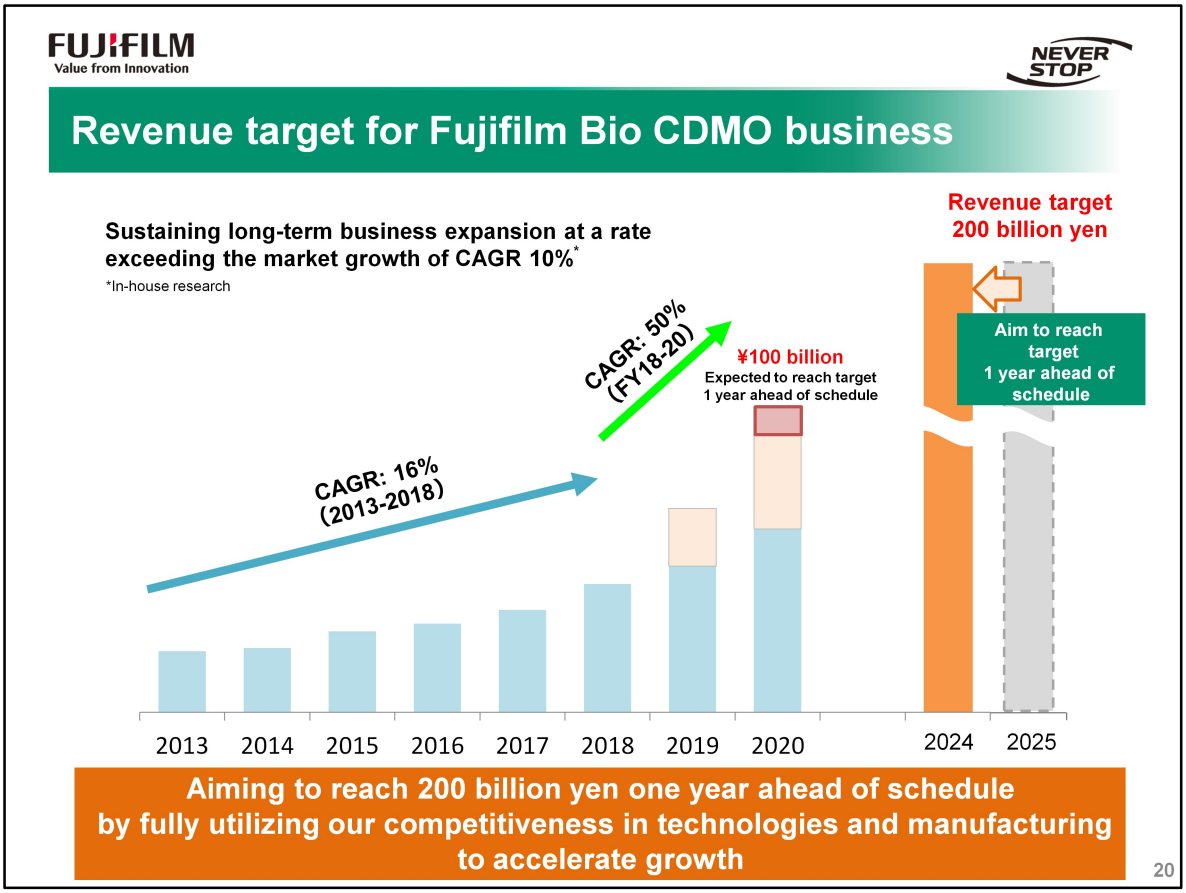
These slides show how we intend to increase our production capacity based on modalities. These charts depict our expansion plan for production capacity of microbial fermentation, mammalian cell culture, gene therapies and vaccines. Between FY2020 and FY2024, our capacity for both microbial fermentation and mammalian cell culture will more than double. For gene therapy drugs and vaccines, it will increase 6.7 times.

We are expanding production capacity at a rate outpacing the market in order to achieve drastic growth.



This slide shows our revenue target for the next five years.

The main message here is about FY2024 and FY2025. While we have previously stated that we aim to reach 200 billion yen in sales by FY2025, we now anticipate to meet this target one year earlier. This forecast is based on stronger demands from our clients as well as our aggressive investments to meet demand.

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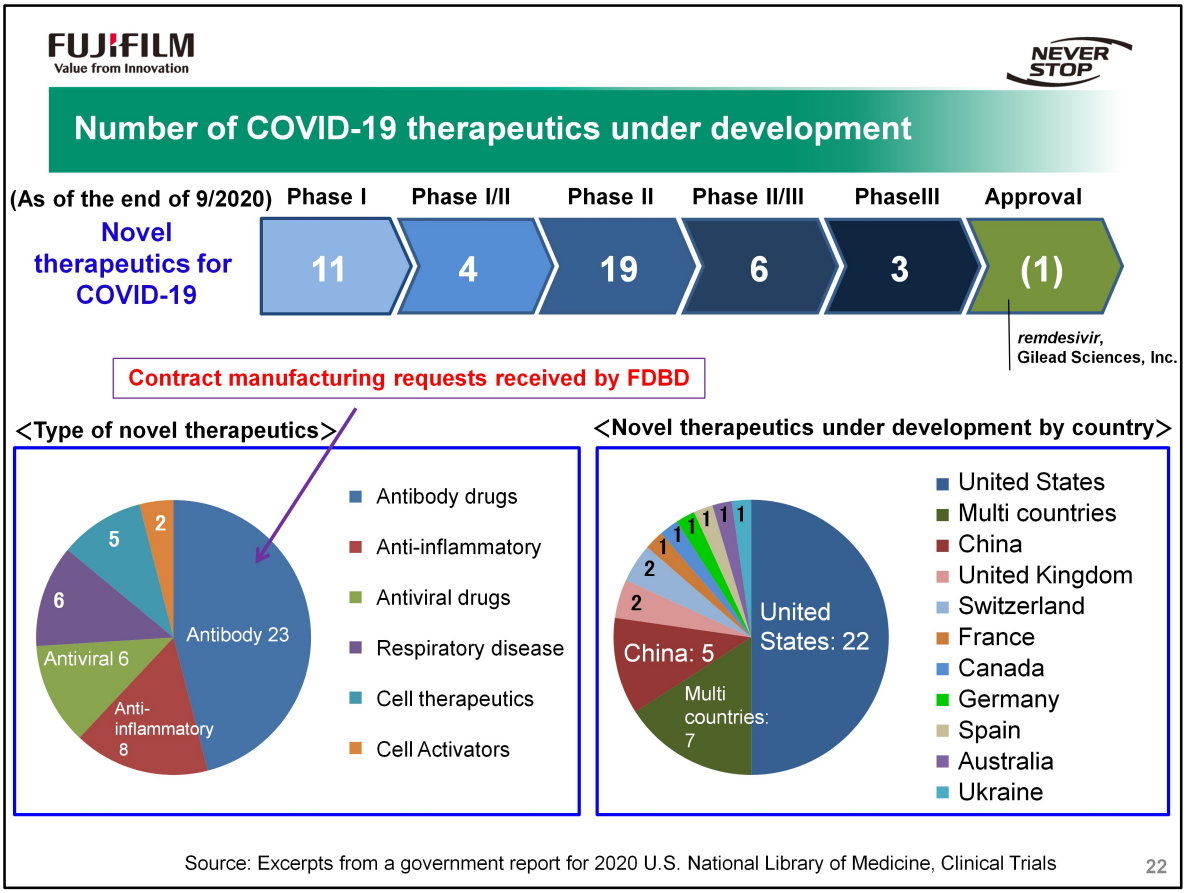
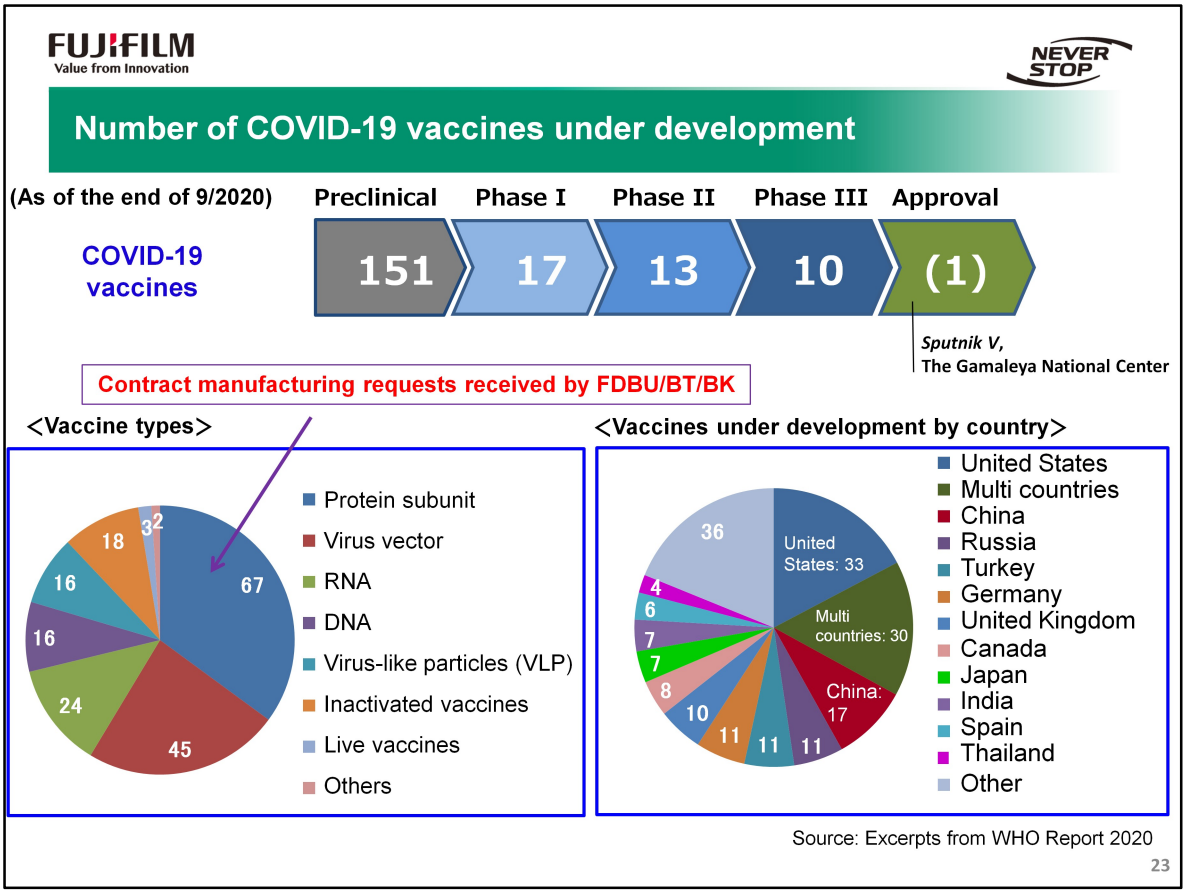
I will now continue to last part of this presentation: The status of our CDMO businesses related to vaccines and therapeutics for COVID-19.



This slide shows the number of novel COVID-19 therapeutics under development, excluding existing drugs.

Based on modality, antibody drugs account for the largest share. We have received contract manufacturing requests for these at our Danish site.



This slide shows the number of COVID-19 vaccines currently under development.

In terms of modality, the biggest share is protein subunit vaccines, followed by virus vector, RNA, DNA, and so on. We have received contract manufacturing requests for these at our North Carolina, Texas, and U.K. facilities.

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COVID-19-related vaccines and therapeutics contracted by Fujifilm

Site	Client	Type	Status	When
North Carolina / USA	Novavax	Vaccine	Started manufacturing a vaccine candidate "NVX-CoV2373" for Phase III clinical trial (up to 30,000 subjects)	Production start
Texas / USA	Tonix Pharmaceuticals	Vaccine	Manufacturing of Tonix's vaccine candidate "TNX-1800"	Not disclosed
Texas / USA	US Government / Novavax	Vaccine	Booked manufacturing capacity until the end of 2021	2021～ (TBD)
Billingham / UK	Novavax	Vaccine	Manufacture of a vaccine candidate to be purchased by the British government (up to 60 million doses). Capable of manufacturing 180 million doses per year. Can be supplied to countries besides the U.K.	2021～ (TBD)
Hillerød / Denmark	COVID-19 Therapeutics Accelerator* / Eli Lilly	Therapeutic	Booked capacity for process development and manufacturing over several years from 2021, for global distribution of COVID-19 drugs specified by the Accelerator →Eli Lilly's antibody drug was selected for manufacturing, which is to begin in April 2021 (announced on October 9, 2020)	Apr. 2021～

*A project for promoting COVID-19 treatment launched by the Bill & Melinda Gates Foundation and others.

All the 4 sites currently have COVID-19-related contracts for vaccines and therapeutics. The Fujifilm Group is committed to contribute to ending the COVID-19 pandemic.

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This last slide is about Fujifilm's CDMO work related to COVID-19 vaccines and therapeutics.

All the four sites have received contracts for COVID-19 related vaccines or therapeutics.

We will manufacture vaccine candidates based on the four orders received in North Carolina, Texas, and the UK. Three of them are from Novavax and one from Tonix.

As for therapeutics, we will manufacture Eli Lilly's antibody in Denmark.

By doing this we, as a group, commit ourselves to contribute to quickly ending the COVID-19 pandemic.

This is the end of my presentation. Thank you very much for your attention.

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Appendix: Details of COVID-19 vaccines

Common issues compared to conventional pharmaceuticals:
- 10 months to 2 years to manufacture and short expiration date (1-3 years stored under refrigeration)
- Governments require stockpiling for fast response to future outbreaks (monitored by the government)

Vaccines (Main categories)	Vaccines (Sub categories)	Description	Track record	Develop-ment period	Productivity	Others
■ Live vaccine 	—	Virus with weakened toxicity	Applied to numerous vaccines, e.g. TB	long	Strict containment needed due to pathogenic virus	
■ Inactivated vaccine 	—	Virus chemically inactivated	Applied to numerous vaccines, e.g. influenza	long		
■ Protein subunit 	—	Partial use of protein in virus	Applied to some vaccines, etc. hepatitis B	mid	Gene transfer Culture and purification	Requiring adjuvant* Price low
■ Virus-like particle (VLP) 	—	Virus protein formulated into particles	Approved for the first time for influenza	mid	Gene transfer Culture and purification	Requiring adjuvant Price low
■ Gene vaccine 	■ DNA	Part of virus's DNA	No track record	short	Gene transfer Culture and purification	
	■ RNA	Part of virus's mRNA	No track record	short	Gene transfer Culture and purification Nano lipid distribution	Requiring refrigeration
	■ Viral vector	DNA/RNA inserted into viruses (Enhanced cell delivery)	Approved for the first time for Ebola	mid	Strict containment needed due to virus Culture / purification (cumbersome)	

*It is also important to develop adjuvants (e.g. aluminium salt) that accelerate the production of neutralising antibodies and enhance their retention.

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Appendix: Details of COVID-19 vaccines 2 (Cost / production process)

・Live vaccines and inactivated vaccines require containment facilities as they require handling of pathogens
・RNA requires dispersion preparation for stabilization, while viral vectors involve cumbersome purification

Vaccine	Anticip-ated cost	Production process					
		Main ingredient	Process 1	Process 2	Process 3	Purifying Process	Drug Product
■ Live vaccines 	low	Pathogenic virus	Infecting eggs / cells with virus	Culturing eggs / cells (Virus generation)	Selecting and culturing viruses of weak toxicity	Collecting and purifying	Formulation
■ Inactivated vaccine 	low	Pathogenic virus	Infecting eggs / cells with virus	Culturing eggs / cells (Virus generation)		Collecting and purifying (+inactivating)	Formulation
■ Protein subunit 	low	Pathogenic gene	Inserting genes into production cells	Culturing production cells (protein generation)		Collecting and purifying	Formulation
■ Virus-like particle (VLP) 	mid	Pathogenic gene	Inserting genes into production cells	Culturing production cells (protein generation)		Collecting and purifying	Formulation
■ DNA 	mid	Pathogenic gene	Inserting genes into e.coli	Culturing e.coli (Replicating DNA)		Collecting and purifying	Formulation
■ RNA 	mid	Pathogenic gene	Inserting genes into e.coli	Culturing e.coli (Collecting DNA)	Using enzyme to synthesize RNA from DNA	Collecting and purifying	Nano dispersion (+lipids)
■ Viral vector 	high	Pathogenic gene	Inserting genes into viruses	Infecting cells with viruses to replicate		Collecting and purifying (virus)	Formulation

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