

H.U. Group IR Day 2022

In Vitro Diagnostics (IVD) Segment:

Update on IVD Strategy

December 9th, 2022

Progress of IVD Strategy (Overview)

H.U. Group Holdings, Inc., Executive Officer (IVD)
Fujirebio Holdings, Inc., President and CEO
Goki Ishikawa



Topic 1: CDMO Strategy and Business Update

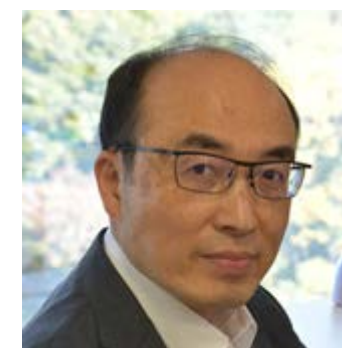
Fujirebio Holdings, Inc.,
Board Member (Global CDMO Business)
Monte Wiltse



Topic 2: R&D Strategy Update

- Neuro/Alzheimer
- Ultra-High Sensitive

Fujirebio Holdings, Inc.,
Board Member and Managing Director (R&D)
Katsumi Aoyagi Ph.D.



Progress of IVD Strategy (Overview)

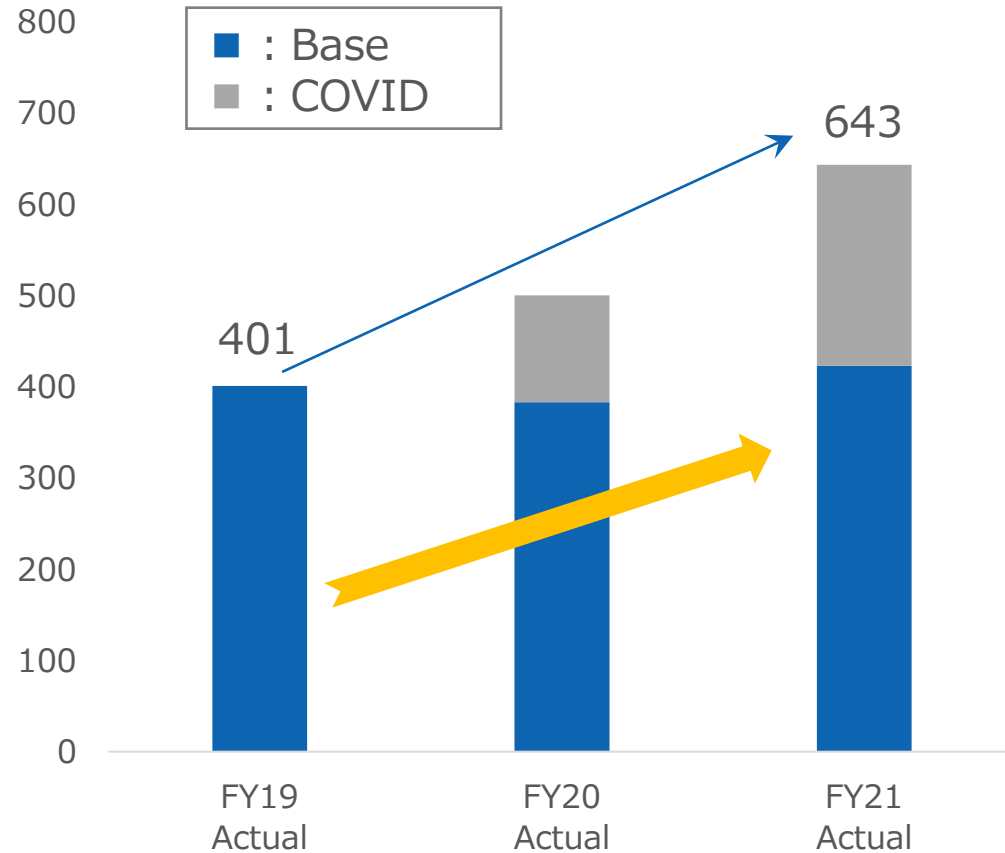
H.U. Group Holdings, Inc., Executive Officer (IVD)

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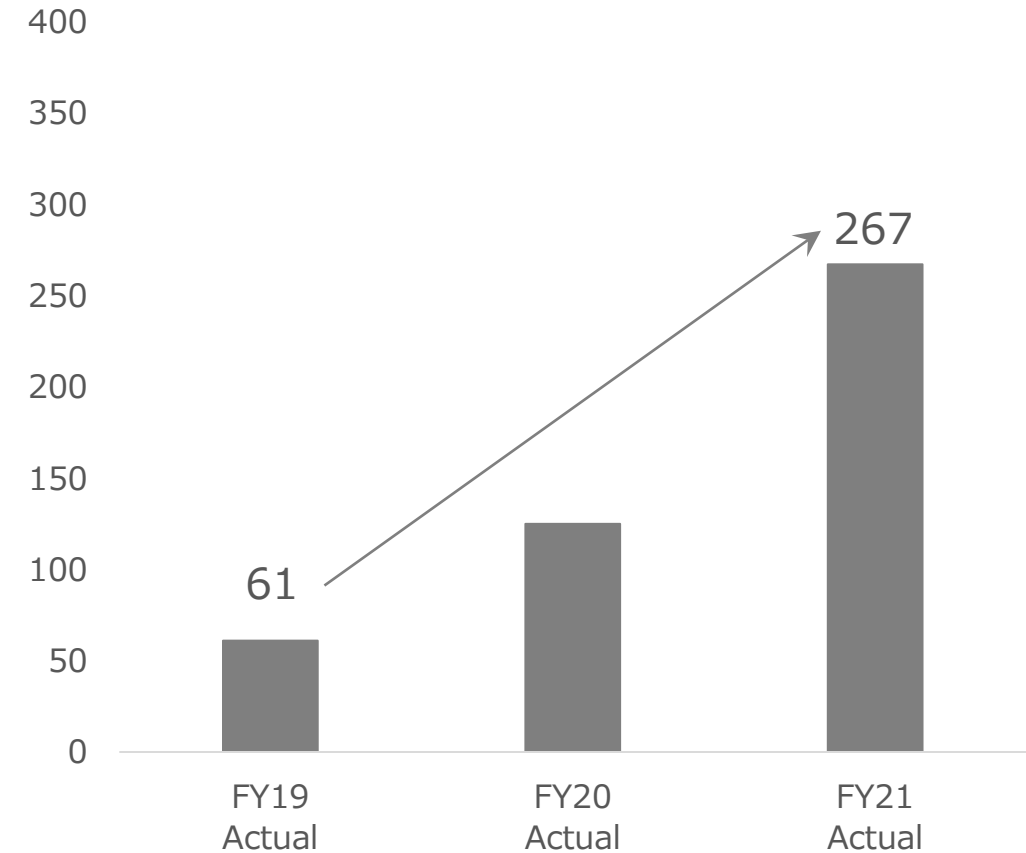
Goki Ishikawa

Financial Performance (FY2019~FY2021)

Revenue (100M JPY)



Operating Profit (100M JPY)



Although COVID sales has big impact, we see **strong growth in Base Business**

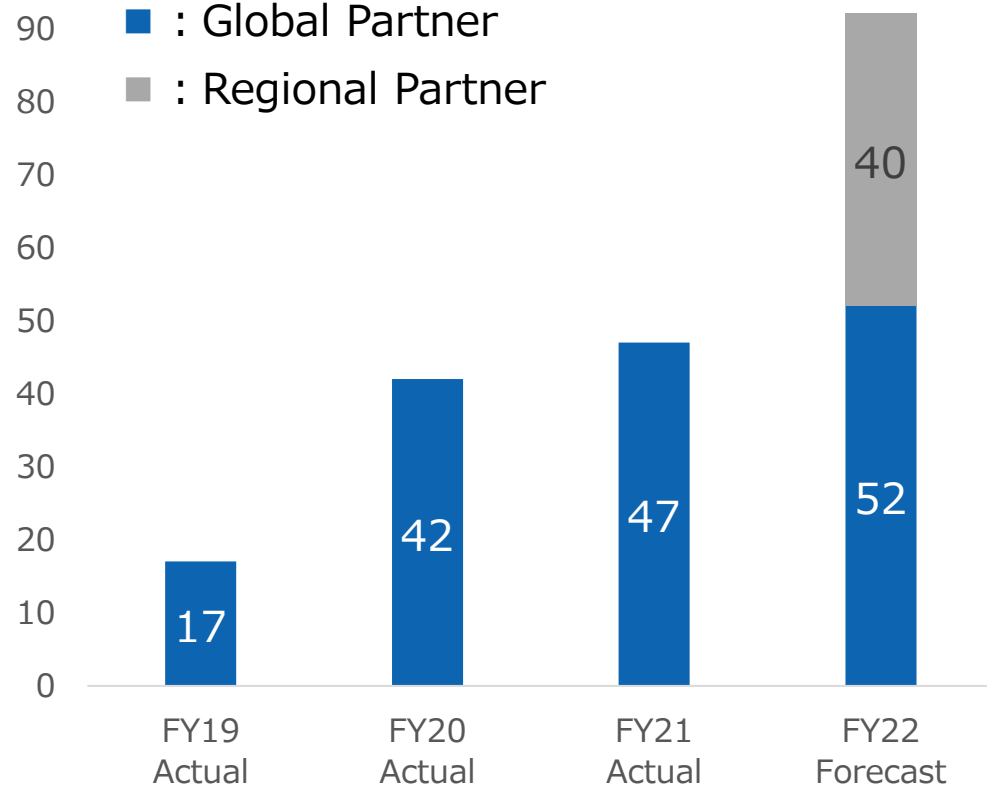
Base Business KPIs – Progress and Forecast (Summary)

CDMO # of Markers (Reagent)

(# of Markers)

100

- : Global Partner
- : Regional Partner

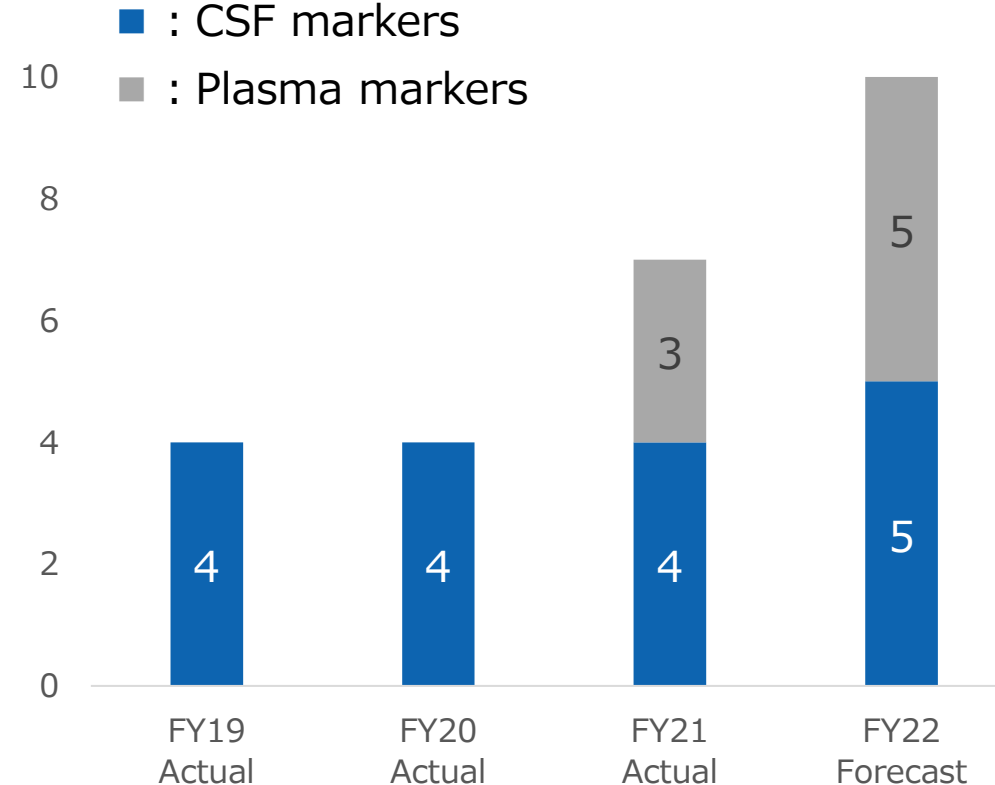


Alzheimer / NEURO # of Lumipulse Markers

(# of Markers)

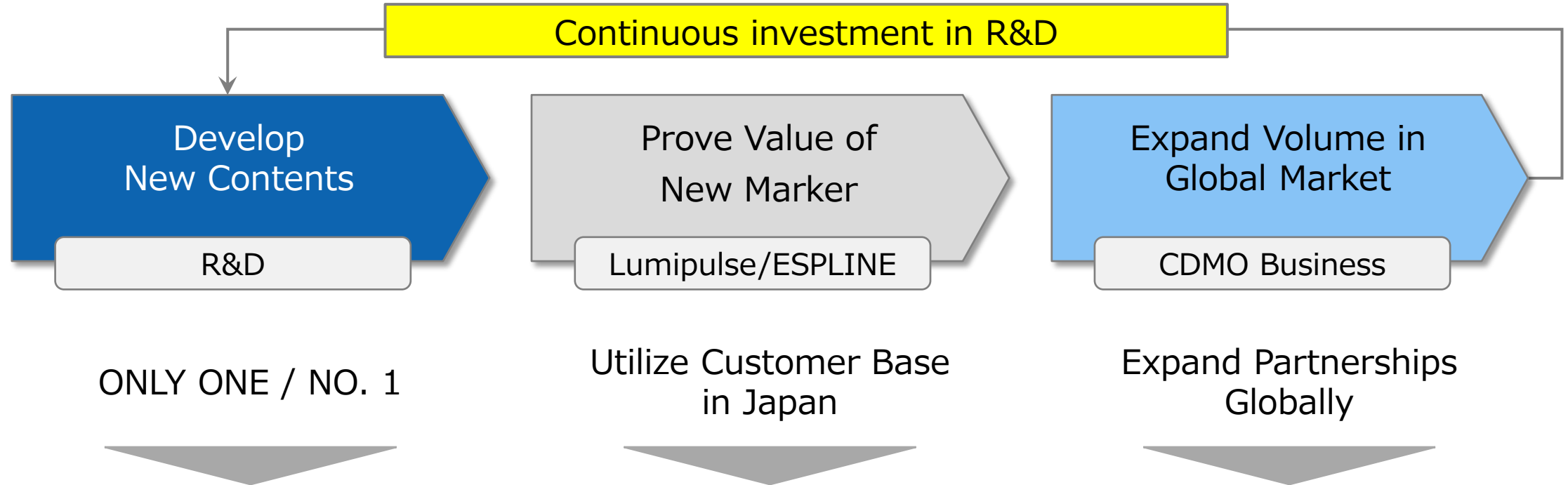
12

- : CSF markers
- : Plasma markers



All KPIs are growing, expected to contribute to Base Business in Short/Mid term

New Global Strategy – Progress



Two Acquisitions completed +



FLUXUS

In-license of technology



New Products being launched

- High sensitive reagent for Lumipulse : iTACT series
- Plasma Alzheimer markers for Lumipulse

Growth in CDMO business

- Continue to gain new projects
- R&D activities in JP/US/EU
- Manufacturing Capacity Investment in JP/US/EU

Strategic Impact from M&A (2 deals)



Strength

- Scientific knowledge of Alzheimer's disease and broad antibody portfolio
- Network of KOLs and global pharmaceutical companies in Neuro field



Impact

- Enhance Alzheimer's marker performance and expand line-up for Lumipulse
- Expand CDMO pipeline
- Strengthen relationships with global pharmaceutical companies
- Acquire world-class talents in this field

FLUXUS

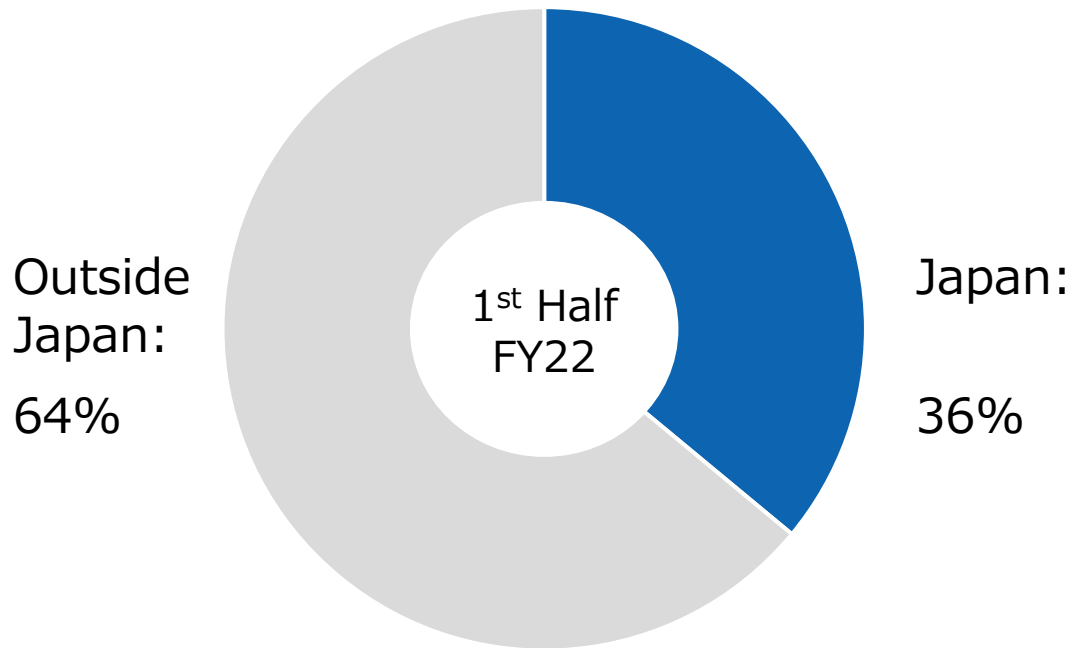
- Specialized in core technologies related to Ultra-High sensitive detection
- “Start-up culture” to challenge new products and business models



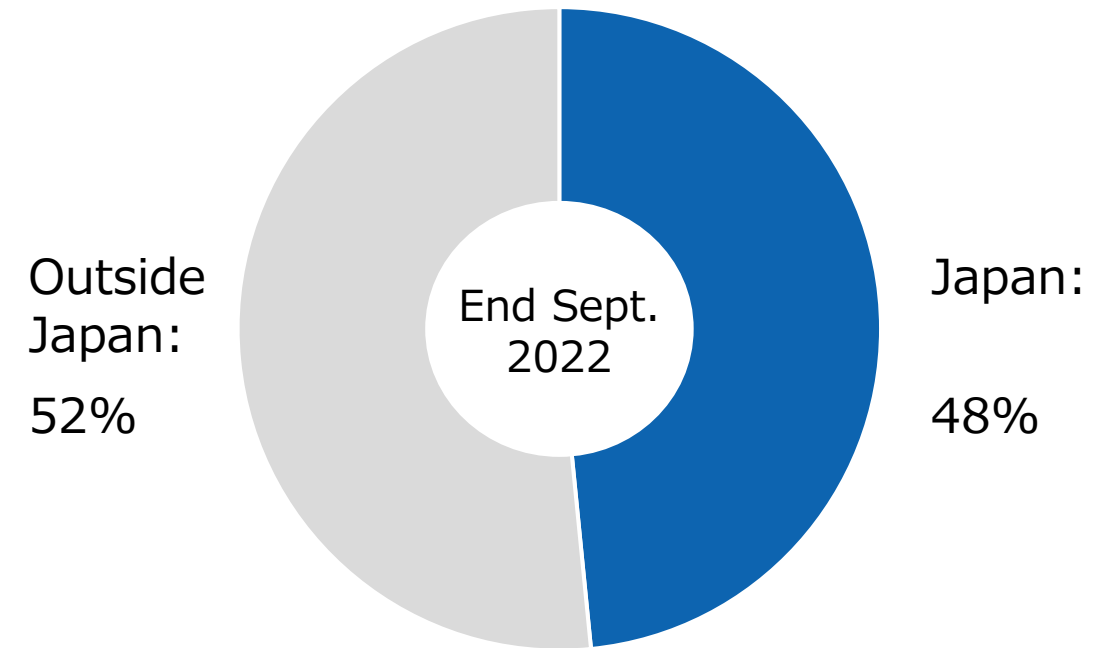
- Bring technology In-house to prepare for launch
- Potential pipeline for New CDMO business
- Gain R&D Base in Silicon Valley
- Acquire world-class talents in this field

Accelerate Growth: Global Organization

Base Business Revenue Ratio

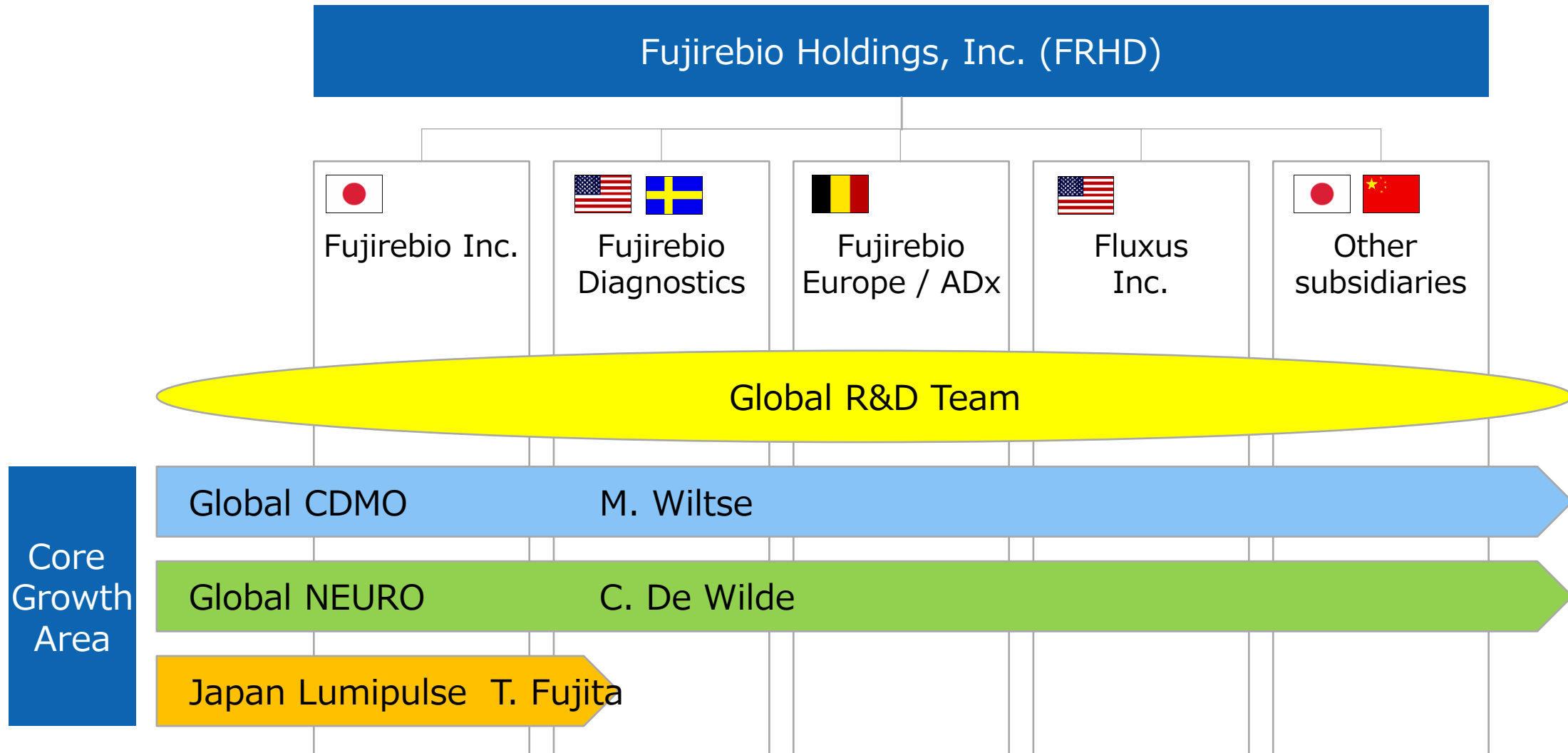


of Employee Ratio



With two companies joining our group,
Non-Japan Ratio for Revenue and # of Employees became Above 50%

Accelerating Growth : Global Matrix Organization



Accelerating Growth : Global Organization Dynamics



- “Top-Down” from Japan will not work
- “Buy-in” in growth strategy is necessary
- “Sense of Unity” within group companies is required



- **Bottom-Up** Growth Strategy (e.g., CDMO, NEURO)
- Drive global strategy by **Non-Japanese**
- **Create Excitement** within group companies

Topic 1: CDMO Business Progress Status Update

Fujirebio Holdings, Inc., Board Member (Global CDMO Business)

Fujirebio Diagnostics Inc., President and CEO

Monte Wiltse

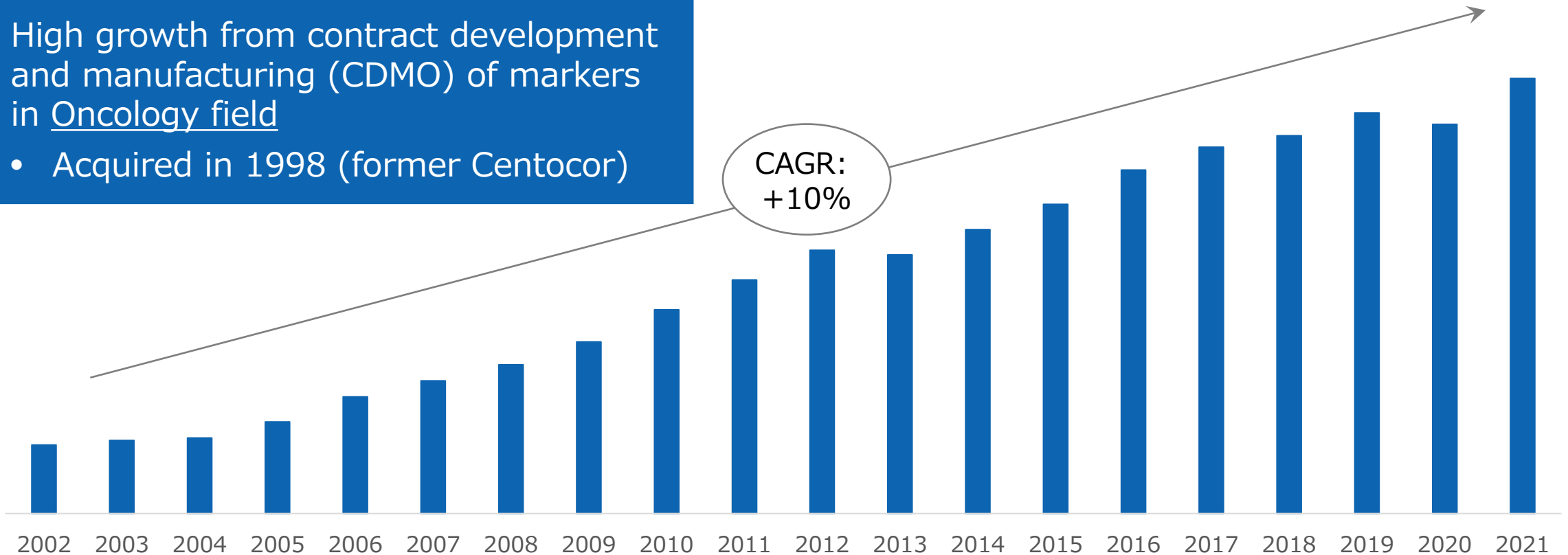
History and background of CDMO in Fujirebio

History of Revenue Growth: Fujirebio Diagnostics Inc. (FDI) (FY2002~2021)

High growth from contract development and manufacturing (CDMO) of markers in Oncology field

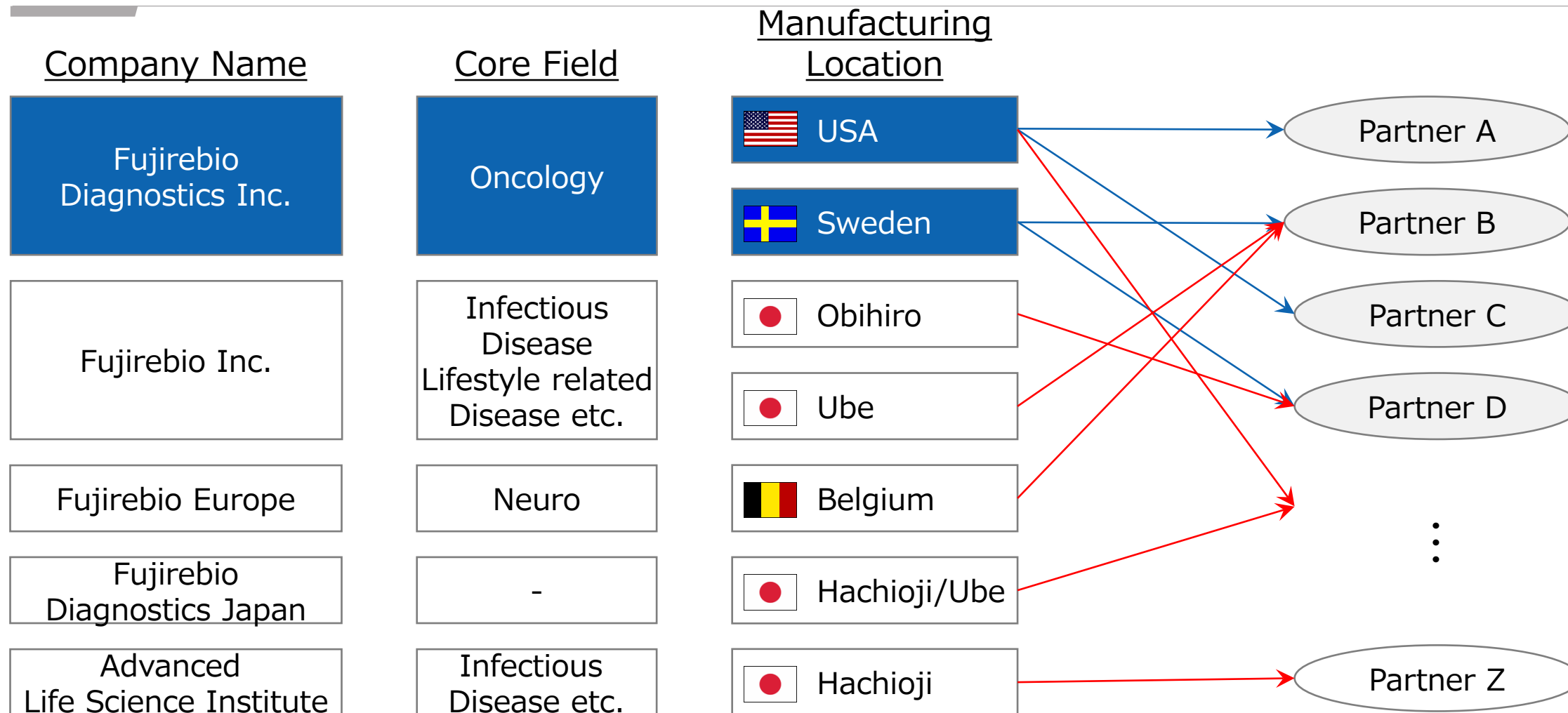
- Acquired in 1998 (former Centocor)

CAGR:
+10%



CDMO has been important business in Fujirebio for more than 20 years

CDMO Strategy and Post COVID Industry Trend



Strong demand from Global Players willing to expand IA menu line-up through outsourcing of development and manufacturing activities (“specialization” in value chain)

Types of CDMO

	Antibody	Reagent	
		Intermediate Products	Finished Kits
Revenue	Low	Mid	High
Profitability	High	Mid~High	Mid
Switching Risk	Low	Low	Very Low
Strategic Point	<ul style="list-style-type: none"> Companies which prefer in-house development and manufacturing Low volume markers 	<ul style="list-style-type: none"> Gain good understanding of development/launch timing Markers which expected volume is above certain level Can receive future CDMO projects from partners 	

Types of CDMO and Trends in Demand

	Antibody	Reagent	
		Intermediate Products	Finished Kits
# of Projects	FY19 : Many FY21 : Many	FY19 : 0 FY21 : 22 +22 items	FY19 : 17 FY21 : 25 +8 Items
Demand Trend	<ul style="list-style-type: none"> Strong demand for unique markers developed by Fujirebio <ul style="list-style-type: none"> Value proven on Lumipulse 	<ul style="list-style-type: none"> Case where local manufacturing is required or can be advantage <ul style="list-style-type: none"> Strong Demand 	<ul style="list-style-type: none"> Partner's resource constraints Strong trust in our quality standards <ul style="list-style-type: none"> Track record (FDA etc.)

Key Investment in Global Locations (1/2)



More than 10 Billion JPY investments to strengthen CDMO business since 2017

- Key Investments are completed

Key Investment in Global Locations (2/2)

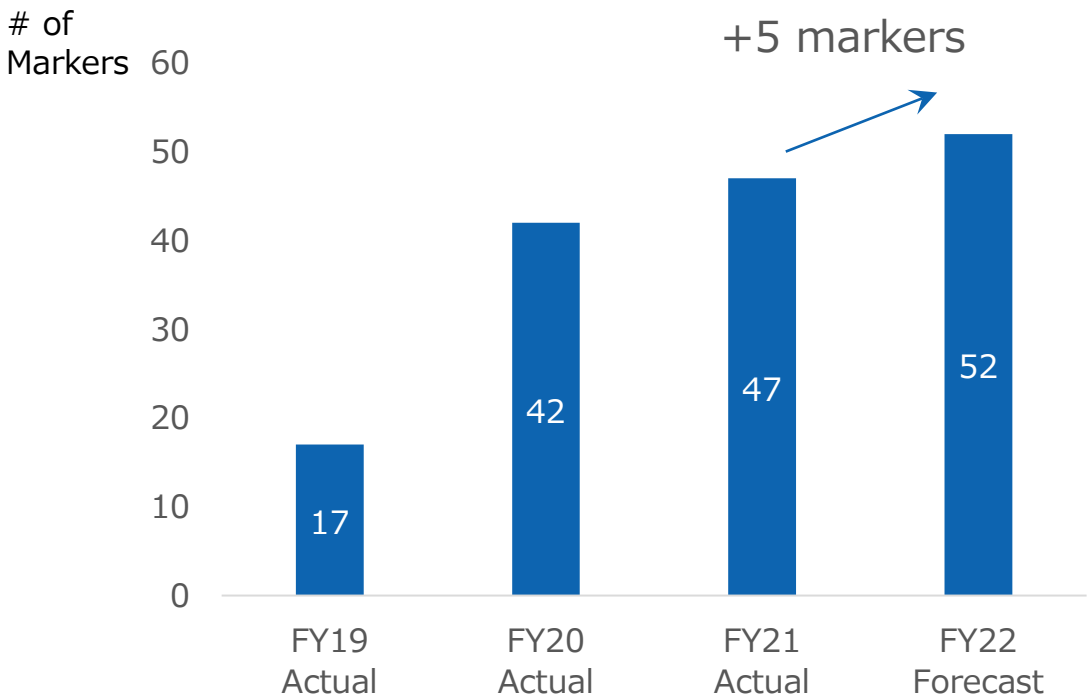


Bioreactors installed in US, Europe and Japan to expand antibody cultivation capacity.

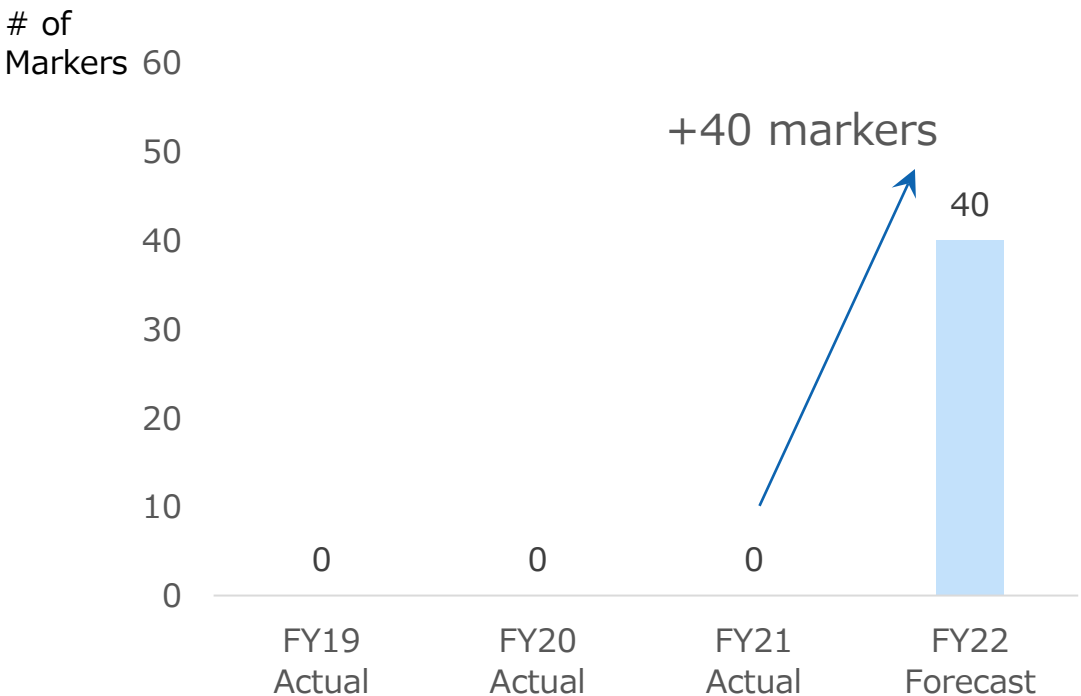
- **50+ units** # Globally top level in diagnostics industry
- Increased capacity by **10 fold**

CDMO: Accumulated # of Markers (Reagent)

Global Partners



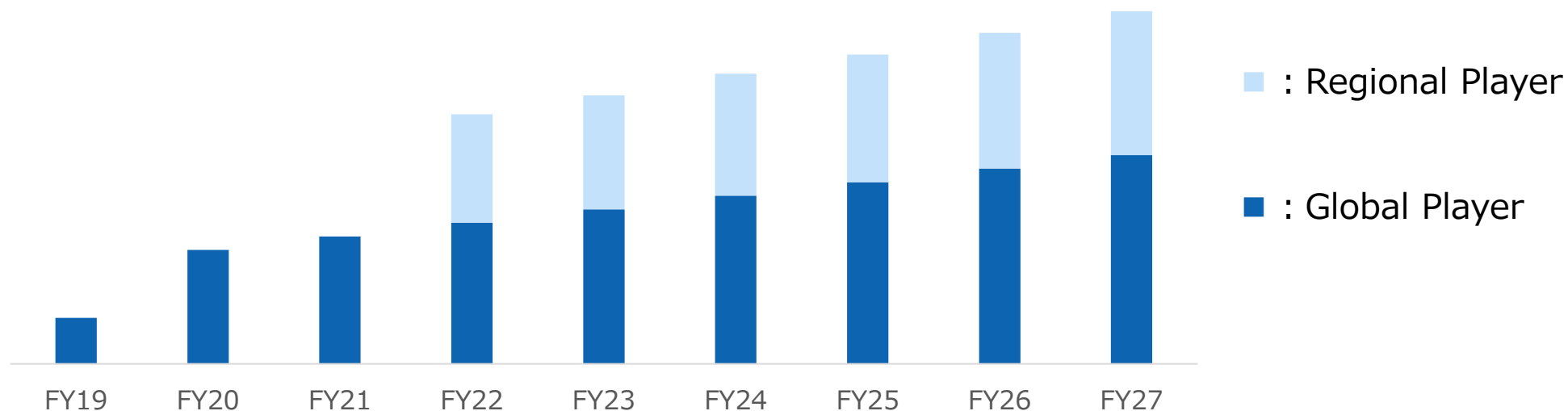
Regional Partners



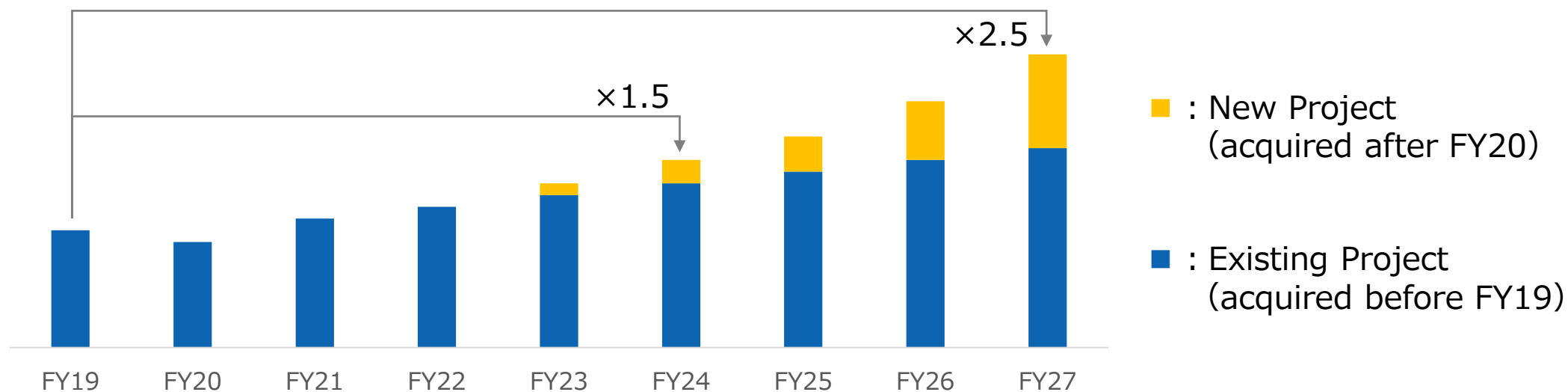
Continuous strong demand from partners for new projects

Link between KPI and Business Growth (Image)

KPI
of Markers (Reagent)



Reference
Test Production Volume



Summary : Growth Scenario

- We believe Reagent CDMO market will continue to grow in diagnostics market.
- Reagent CDMO business in Oncology field has been business within Fujirebio for **20+ years**.
- Key success factor in reagent CDMO is to continuously expand portfolio of materials and technologies which **other companies do not have**.
 - There is high demand for raw materials, technologies, and markers we have today.
 - Acquisition of **ADx** will enable us to capture demand for raw material supply and reagent development and manufacturing in the Alzheimer's disease area.
 - Acquisition of **Fluxus** will enable us to add Ultra-High sensitivity detection technology and corresponding reagents to future CDMO pipeline.
- Fujirebio successfully **expanded manufacturing capacity** for raw materials and reagent manufacturing through investment over the past five years (buildings, bioreactors, etc.)
- We will continue to capture market demand through growing KPI (Accumulated # markers (reagent)) and to successfully complete existing projects working closely with our partners.

Topic 2: R&D Strategy and Progress

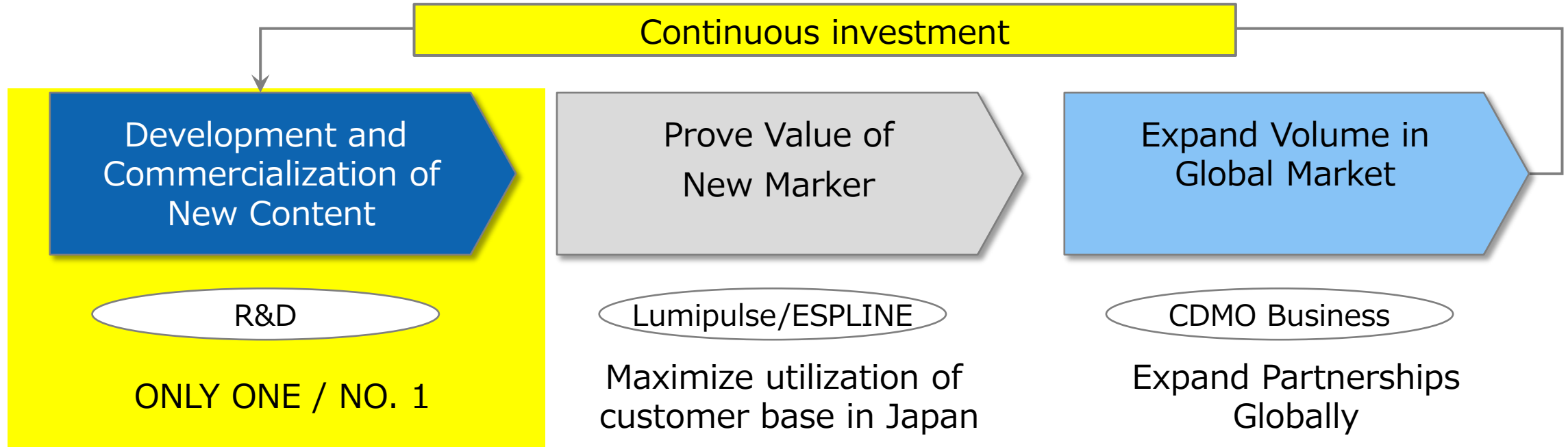
Alzheimer/NEURO, Ultra-High Sensitive Detection Technology

Fujirebio Inc.,

Board Member and Managing Director (R&D)

Katsumi Aoyagi Ph.D.

R&D at New Global Strategy

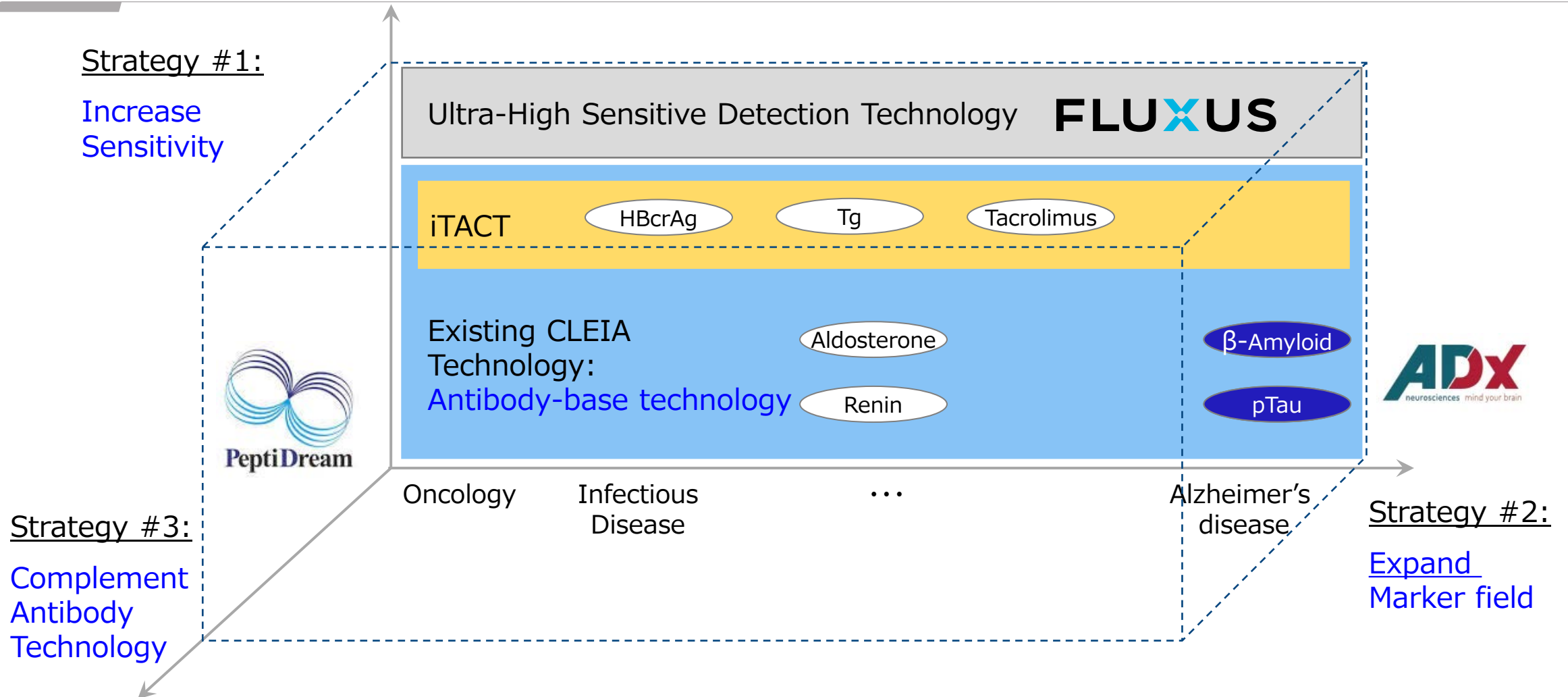


Basic Policy :

"Contribute to more accurate testing, wider clinical applicability, and correct clinical diagnosis"

- Accurately measure & detect analytes presented in specimens
- Pursue novel clinical usefulness of each marker/test

R&D Technology / Business Strategy



Always be Ahead of the Game

All output can be supplied to our global partners through CDMO model

ONLY ONE / NO. 1

Strategy ① Increasing Sensitivity

- **iTACT : Effective pre-treatment for high sensitive test developed by FRHD**
 - Patent: HBcrAg (Hepatitis B), Tg (Thyroid Cancer)
- **Fluxus : Single molecule detection method**
 - Accelerate new platform development by Ultra-High sensitive technology

Strategy ② Marker Field Expansion

- **Low molecular sandwich method :**
 - Patent: Aldosterone(Hypertension), Renin(Hypertension), 25-OH Vitamin-D(Osteoporosis)
- **ADx raw material and clinical know-how :**
 - Accelerate Neuro/Alzheimer markers through

Strategy ③ Complement Anti-body Technology

- **Application of PeptiDream core technology to diagnostic reagents :**
 - Complement Ab-based reagents development with peptide
 - Practical application to new biomarkers, more stable production and supply chain

Alzheimer/NEURO : Strategy and Progress

CSF diagnostic
Automation•IVD

Successfully developed
4 markers for Lumipulse

- β -Amyloid 1-42
- β -Amyloid 1-40
- pTau181
- Total Tau

Obtained IVD approval in major
countries

- FDA
- CE mark (IVD-R)
- PMDA

Expand Plasma line-up
in addition to CSF

Accelerate developing markers
for Lumipulse

- Launched 3 markers
 - β -Amyloid 1-42
 - β -Amyloid 1-40
 - pTau181

- Launch scheduled by March 23
 - More than 3 markers

Expand Plasma line-up
by Ultra-High sensitive
detection

Develop new platform and
dedicated reagents

- Launch RUO by FY23
- Alzheimer's disease markers
are expected

→ In progress as scheduled

Accelerate through acquisition of ADx/Fluxus

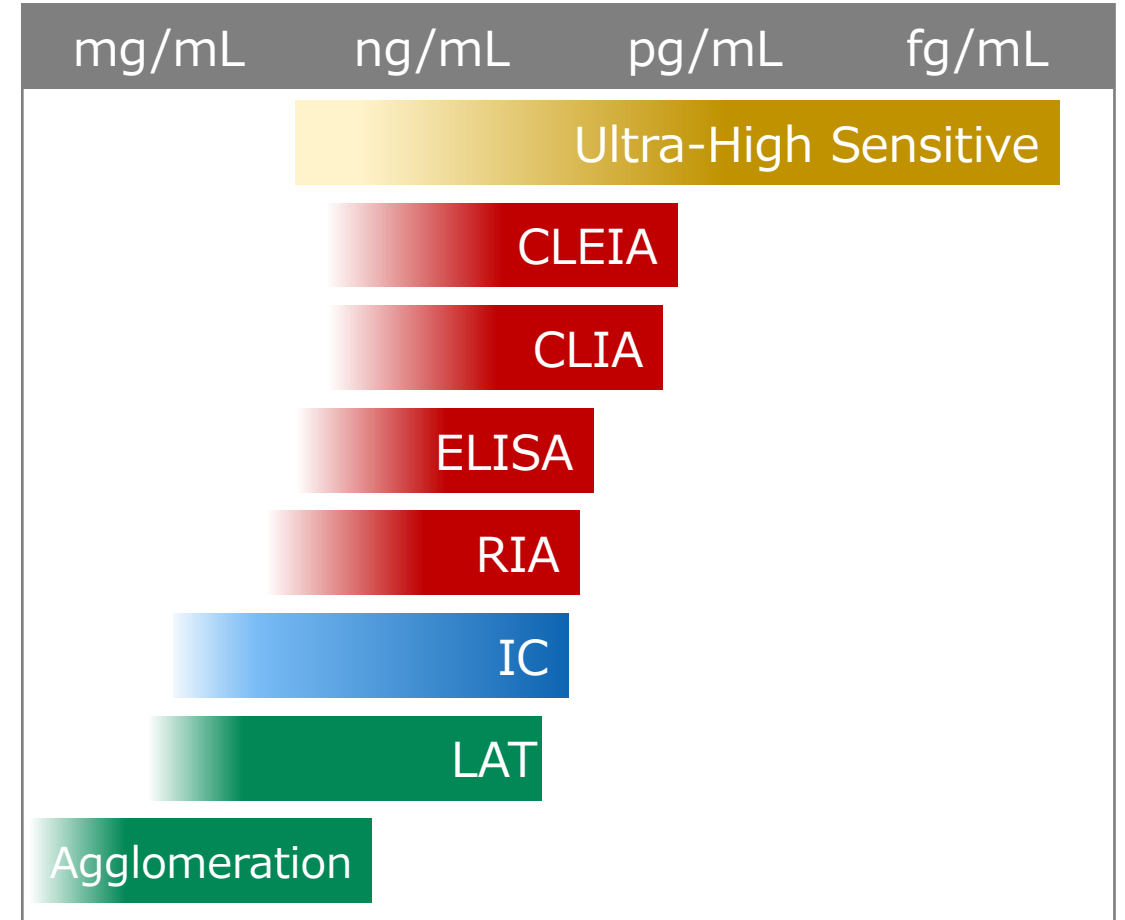
	CSF Markers	Blood Testing Markers	
IVD	<ul style="list-style-type: none">• β-Amyloid 1-42• β-Amyloid 1-40• pTau181• Total Tau	<div>※ Gain data and regulatory submission, based on strategic story</div>	
RUO	<ul style="list-style-type: none">• Neurofilament Light (NfL) <div>Black : Launched Blue : In development</div>	<ul style="list-style-type: none">• B-Amyloid 1-42• B-Amyloid 1-40• pTau 181• pTau 217• pTau 231	<ul style="list-style-type: none">• GFAP• BDNF• ApoE4• ApoE• Neurofilament Light (NfL)

Launch at least 3 RUO markers by end March 2023

Strategic Point

- **Develop new platform by Fluxus technology**
 - Single molecule detection method
 - Launch RUO by FY23
- **Develop markers with clinical significance**
 - Alzheimer's disease, Oncology, Infectious diseases, etc.
- **Next generation platform strategy**
 - Combination of existing Chemiluminescence method and Ultra-High sensitive
- **Expand line-up for CDMO in Mid-term**
 - Supply core technology and reagents to partners globally

Expected Benefit



Ultra-High Sensitive Detection: Mid term Development Strategy

Base of Competitiveness for Next 10 Years

Complete RUO development
Alzheimer's disease field

FLUXUS



Complete and launch RUO with our concept

- End of FY23 (by Mar 24)
- Launch 3 markers for Alzheimer
 - Use best Antibody in group

Expand markers in
Oncology/Infectious disease

FLUXUS



Realize new value which other players could not realize

- New markers in oncology and infectious disease fields

Next Generation Platform
"The Next Standard"

LUMIPULSE®



FLUXUS

Set Global Standard for
"Post Chemiluminescence"

- Supply all products to partners through CDMO business model

Summary

- **Fujirebio Global R&D team** will focus on launching new value-added products
 - Strategy: “Increase Sensitivity”, “Expand Marker Field”, “Complement Antibody Technology”
- **Alzheimer/NEURO**: Expand line-up of **Plasma markers for Lumipulse** and supply globally
 - Accelerate Lumipulse Reagents Development through using best Antibody including ADx
 - Add at least 3 RUO markers by the end of FY2022 (by Mar 2023)
- **Ultra-High Sensitive Detection**: Launch product and **create new market**
 - Fluxus will launch RUO instrument and reagents by end of FY2023 (by Mar 2024)
 - Expand marker line-up and supply to global players through CDMO business model
- **R&D is the “ENGINE” to our global strategy**
 - Establish our competitiveness in global market through constantly **challenging new possibilities** and **to be ahead of the game**

Summary

H.U. Group Holdings, Inc., Executive Officer (IVD)

Fujirebio Holdings, Inc., President and CEO

Goki Ishikawa

Summary

- Good performance of IVD segment, especially, **base business growing**
 - KPIs for Base Business continues to grow. **Our Global Strategy is working**
- With 2 companies joining Fujirebio, **New Global Structure started from July 2022**
 - **Global Leadership** will accelerate growth in our core segment
- **CDMO will continue to lead our growth** through leveraging our unique materials
 - Through CAPEX in past 5 Years, we successfully expanded our capacity
- Our **Global R&D team** is focusing on development of **Neuro and Ultra-High Sensitive Products**
 - Once launch on own platform, we will aggressively approach global partners through CDMO
- **ONLY ONE / NO. 1 Technology**, established through combination of M&A, technology license and in-house technology, is the foundation of our sustainable technology superiority.
- In addition to achieving this medium-term goal, **we will continue to grow revenue in mid-single digits and achieve 20~25% Operating Profit Margin beyond next medium-term**

