

H.U. GROUP / IR DAY 2021
IVD BUSINESS: STRATEGY AND KEY UPDATES

December 8th , 2021

GOKI ISHIKAWA

AGENDA

- ABOUT IVD BUSINESS IN H.U. GROUP
- MARKET ENVIRONMENT CHANGE IN POST COVID
- NEW GLOBAL STRATEGY (FY2020~)
- KEY TOPICS AND UPDATES
- SUMMARY

ABOUT IVD BUSINESS IN H.U. GROUP (FUJIREBIO)

IVD BUSINESS (FY2020)

- REVENUE: 50.0B JPY
- OP : 12.8B JPY

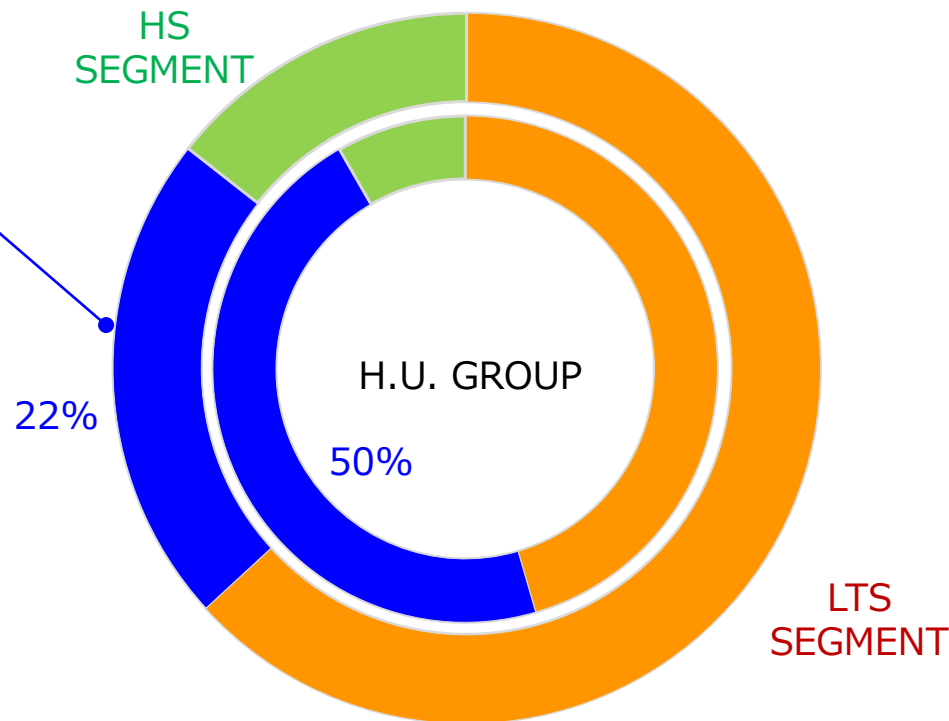
Note:

- Outside: Revenue ratio
- Inside: OP ratio

ABOUT THE BUSINESS

- Business targeting Immunoassay (IA) testing in global diagnostics market
 - Global IA Market: \$28 Billion, CAGR: +8%
- Development, manufacturing and sales & marketing of IA analyzers and reagents
 - Analyzer + (Closed) Reagents
 - Reagents: Infectious Disease, Oncology, Fertility, Cardiac, Endocrine, Lifestyle related, Alzheimer
- Key Players: Roche, Abbott, Siemens Healthineers, Beckman Coulter etc.
- Fujirebio's portfolio (FY2020)

• Lumipulse (Japan/Global)	45%
• OEM ("CDMO") / Raw Materials	33%
• Other (POCT Espline etc.)	22%



FUJIREBIO PORTFOLIO (FY2019; PRE-COVID)

★: Low ★★: Mid ★★★: High

		REVENUE (BILLION JPY)	SEGMENT OP MARGIN	MARKET GROWTH RATE	FUJIREBIO GROWTH RATE
LUMIPULSE (LP)	Japan (Reagents/Analyzers)	13.5	★★	★	★
	Global (Reagents/Analyzers)	2.2	★	★★	★★★
CDMO/ RAW MATERIALS	CDMO (Reagent OEM)	9.4	★★	★★★	★★★
	Raw Material Sales	6.4	★★★	★★	★★
OTHER	POCT (COVID not included)	1.0	★	★★	★
	Other	7.5	★	★	★

Japan and Outside Japan Sales Ratio is about 50:50.
 Need to increase Outside Japan Sales Ratio going forward.

MARKET ENVIRONMENT CHANGE IN POST COVID

Our Hypothesis

Intense competition to gain customers

- Providing Total solution across multiple testing fields becomes common practice
 - Consolidation of IVD providers (M&A)
- Price Competition
- Regulatory process becomes challenging in each market

Division of labor in Diagnostics industry

- Division of labor in global diagnostic industry, similar to pharmaceutical industry
 - Demand to expand menu line-up quickly
 - Outsource new marker research, reagent development, and manufacturing process

Change in testing field landscape

- Polarization of testing menu
 - Routine / Specialty
- New entrants to IA field
- Demand for instrument consolidation; Improve workflow
 - Lack of space
 - Cost to recruit and train lab technicians

Implication to strategy

Broad product line-up and **Scale** will become Key Success Factor

- Difficult to grow just with product offering in IA

Diagnostic CDMO market will grow on global scale

- Trend observed today

Platform strategy will become key strategic topic for all players

- **Post Chemiluminescence** technology

NEW GLOBAL STRATEGY: FUJIREBIO'S "CORE COMPETENCE"

ABILITY TO **DEVELOP UNIQUE MARKERS/TECHNOLOGY**

- R&D teams in Japan/ Europe and US
- Patents
- In-house manufacturing Antibodies/Antigens etc.

ABILITY TO **DEVELOP "PRODUCTS"**

- Capable to customize for various platforms
- High quality standards and stable manufacturing capability

ABILITY TO **PROVE VALUE OF NEW MARKERS DEVELOPED**

- Prove value on own platform (Lumipulse/Espline)
- Fast evaluation and market development through introduction in SRL/H.U. Group

Fujirebio has **strengths in Up-Stream Process** within Diagnostic Industry.

Unique position within Global Industry

STRENGTHS: DEVELOPING UNIQUE MARKERS (“ONLY ONE” MARKERS)

	SANDWICH METHOD	iTACT METHOD	OTHER METHODS
--	-----------------	--------------	---------------

Aim

Method to measure with high sensitivity and high specificity	Pre-treatment method to gain high sensitivity and high specificity	High sensitivity technology through good understanding of character
<ul style="list-style-type: none"> High performance Antibodies developed which cannot be done by other companies 	<ul style="list-style-type: none"> Technology developed by Fujirebio to take away impact of interference 	<ul style="list-style-type: none"> Variants; Destroy virus structure to measure target effectively

Markers

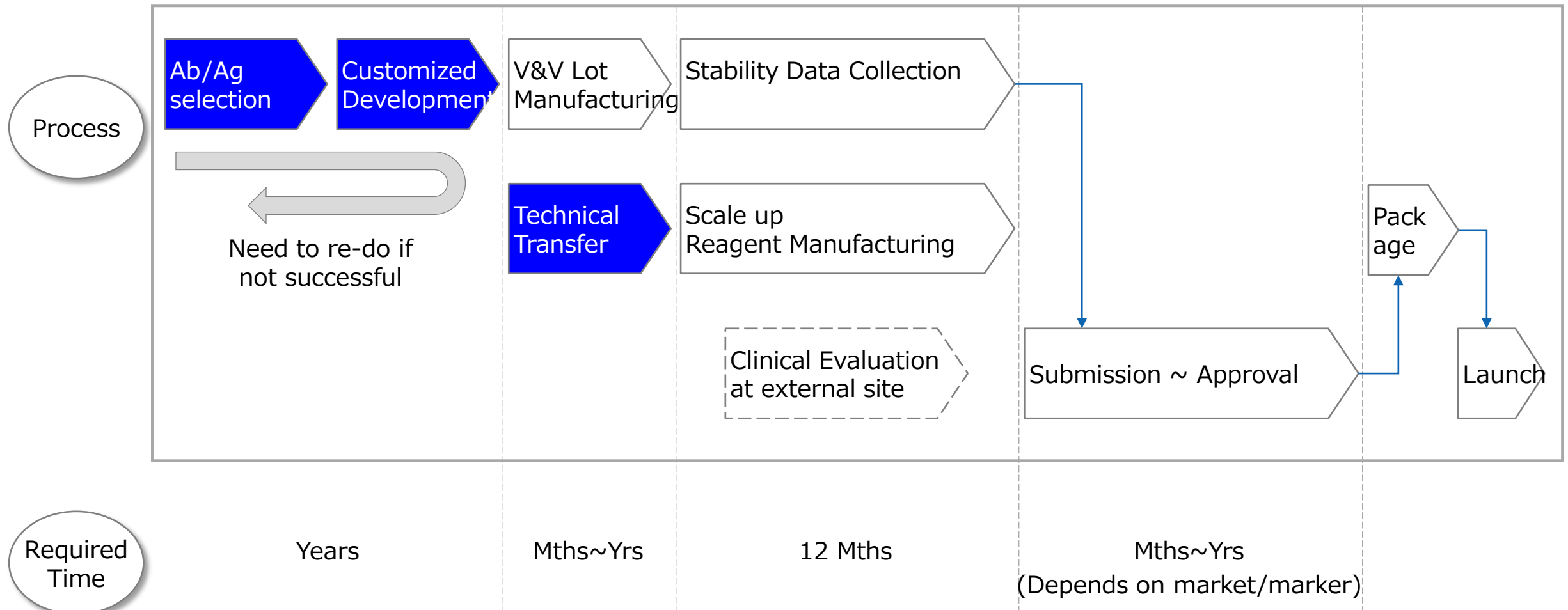
- | | | |
|-----------------------|----------------------|-----------------|
| ★ 25-OH VitaminD | ★ Thyroglobulin (Tg) | ★ HE4 |
| ★ Aldosterone | ★ HBcrAg | ★ HBsAg-HQ |
| ★ Renin | | ★ SARS-COV-2 Ag |
| ★ Type IV Collagen 7S | | |

★ Patent

★ Patent submitted

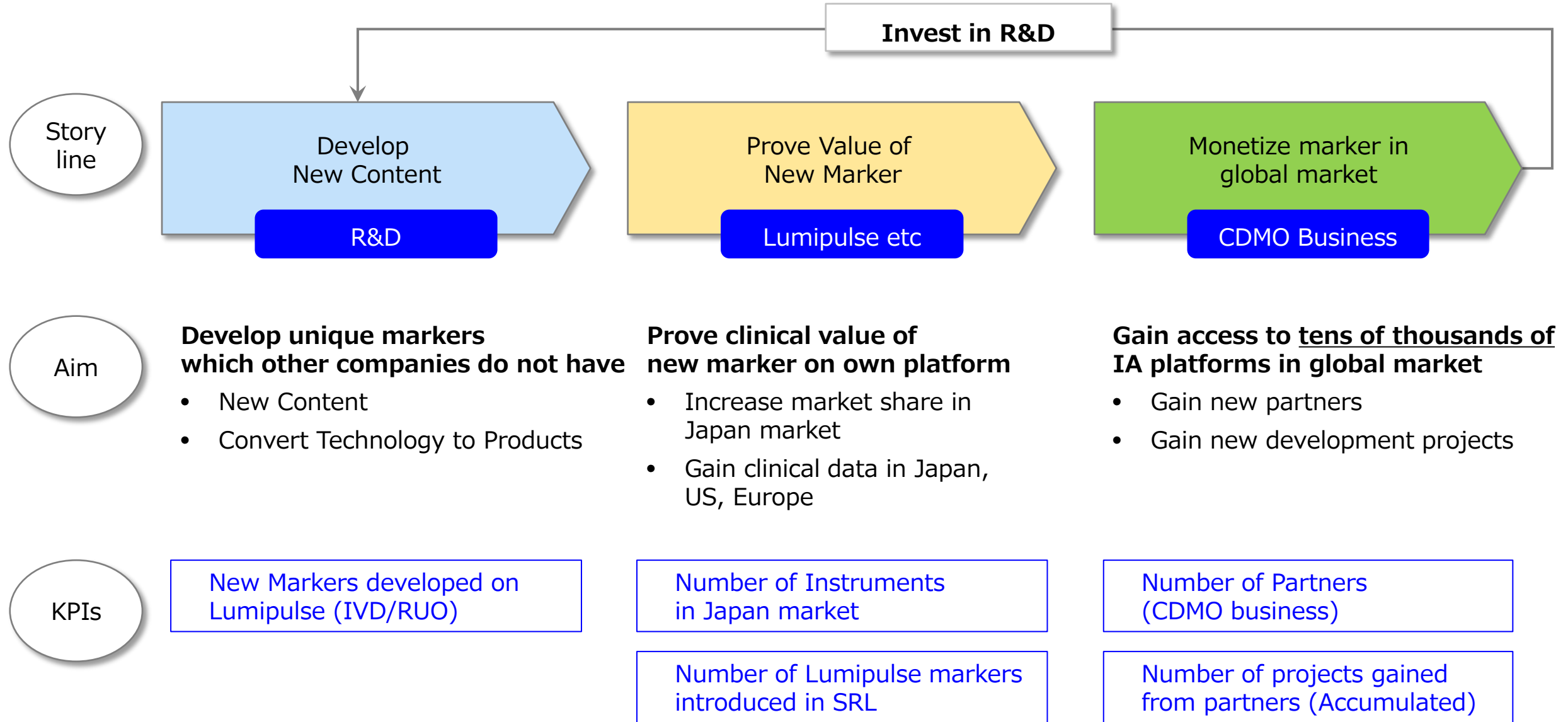
Over 10% of Fujirebio Revenue is spent on R&D activities
on an annual basis in Japan, US and Europe

STRENGTHS: PRODUCT DEVELOPMENT KNOW-HOW

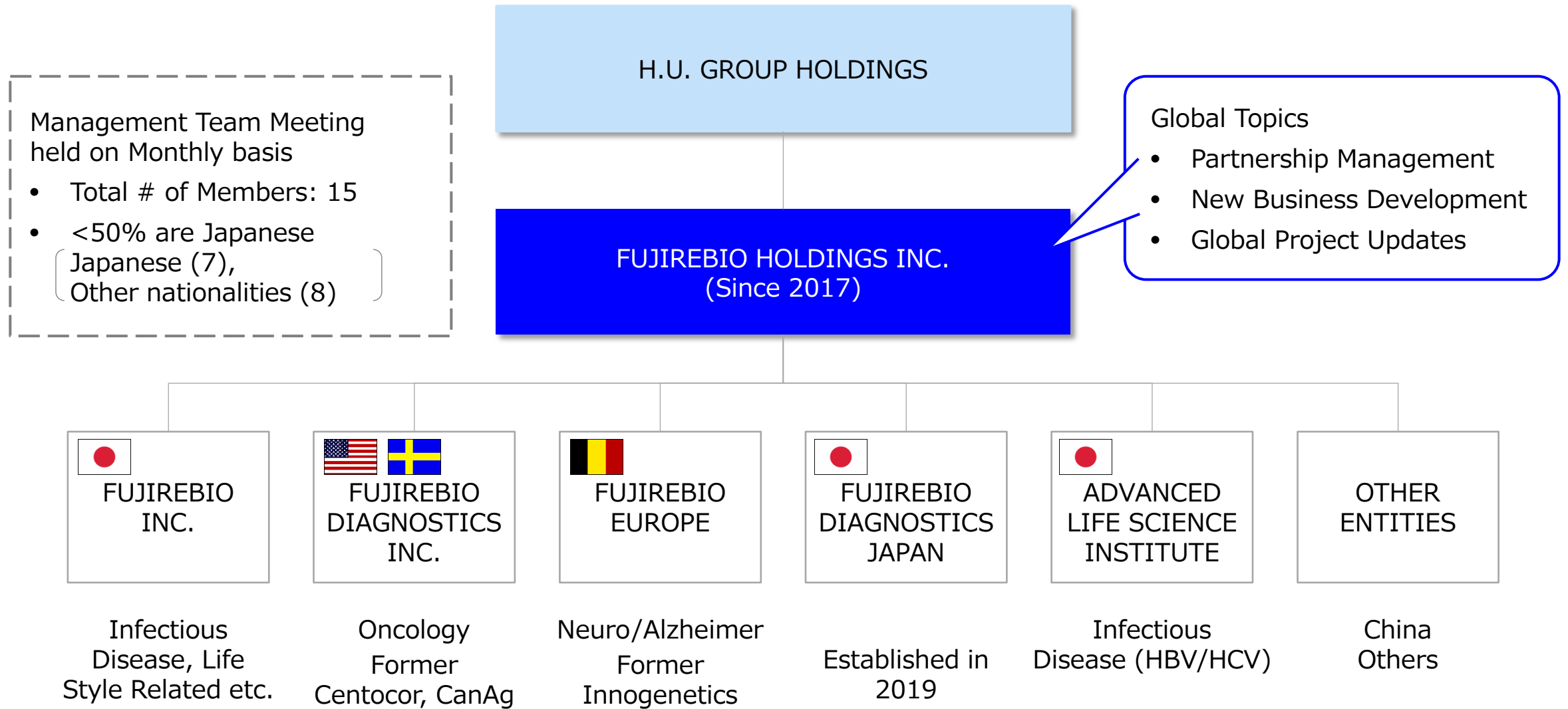


Strong skill set in Product Development and Production is
Know-How gained through 30 Years of Lumipulse/Espline Business

GROWTH STRATEGY: SUMMARY

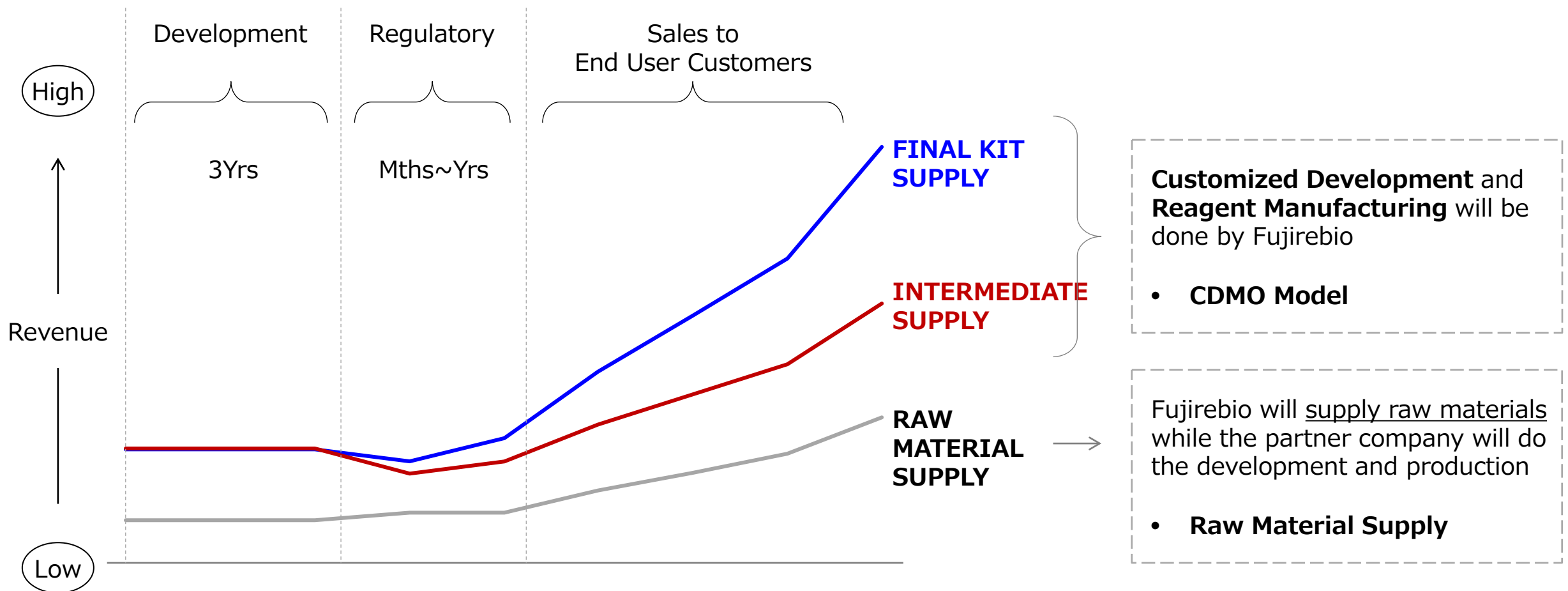


GLOBAL ORGANIZATION STRUCTURE



KEY TOPICS AND UPDATES

PROGRESS (1): CDMO BUSINESS (TYPES OF BUSINESS)



We aim to create a long-term partnership with our partners.

What makes us different are; i) Value proven on Lumipulse, ii) New marker proposal, iii) Multiple sites globally

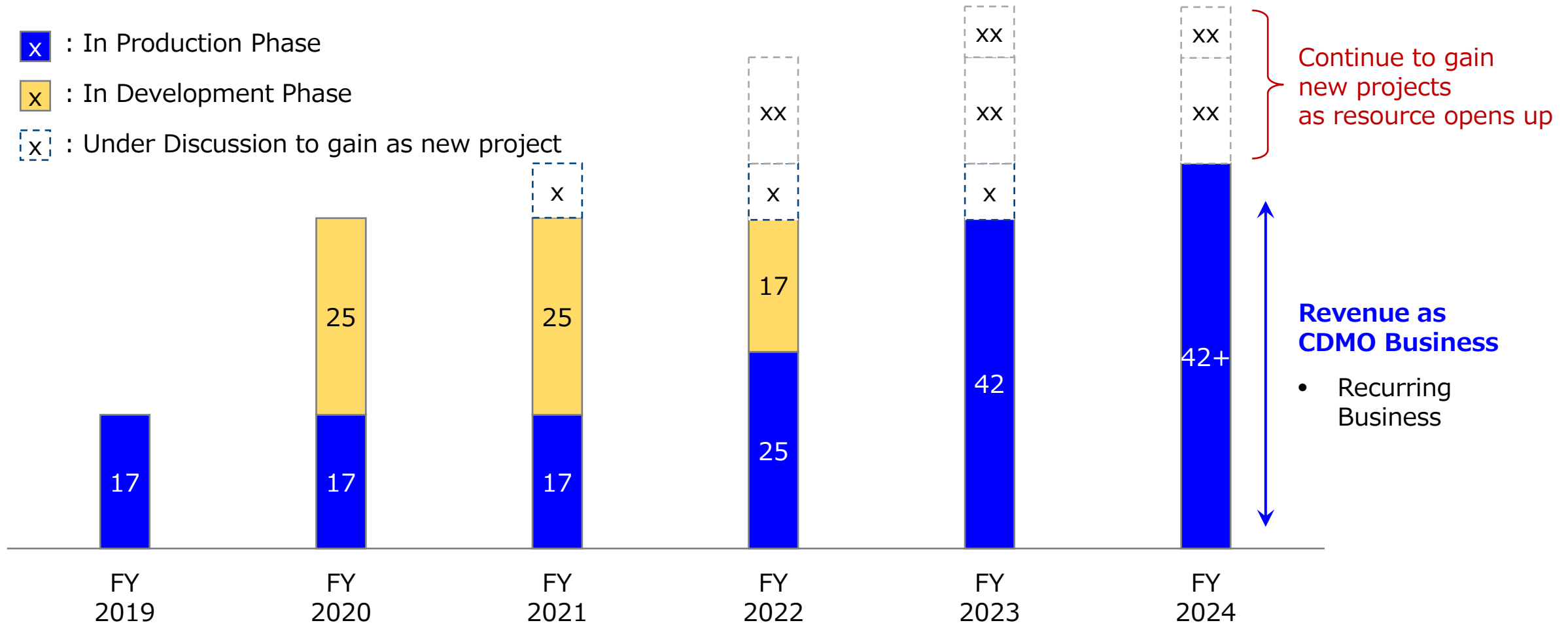
PROGRESS (1): CDMO BUSINESS (GROWTH SCENARIO: KPI)

◆ NUMBER OF DEVELOPMENT PROJECTS GAINED FROM PARTNERS (ACCUMULATED)

x : In Production Phase

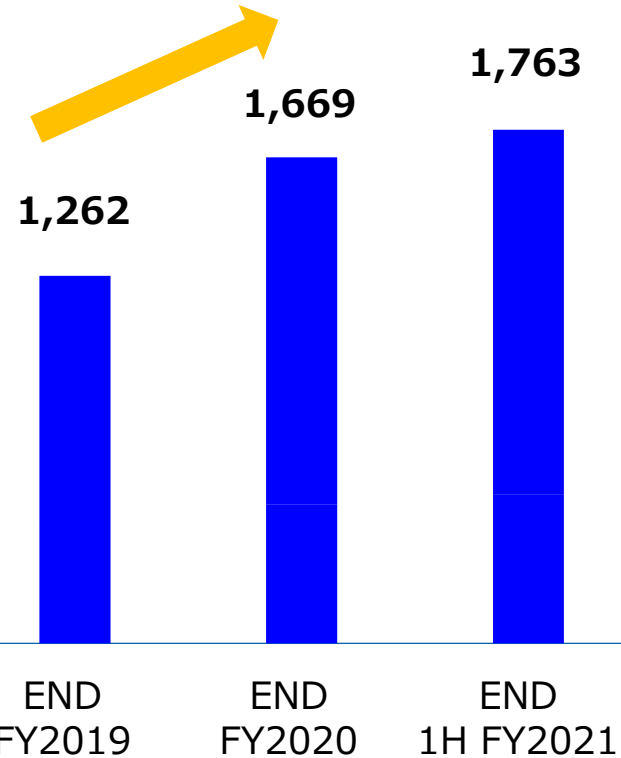
x : In Development Phase

x : Under Discussion to gain as new project

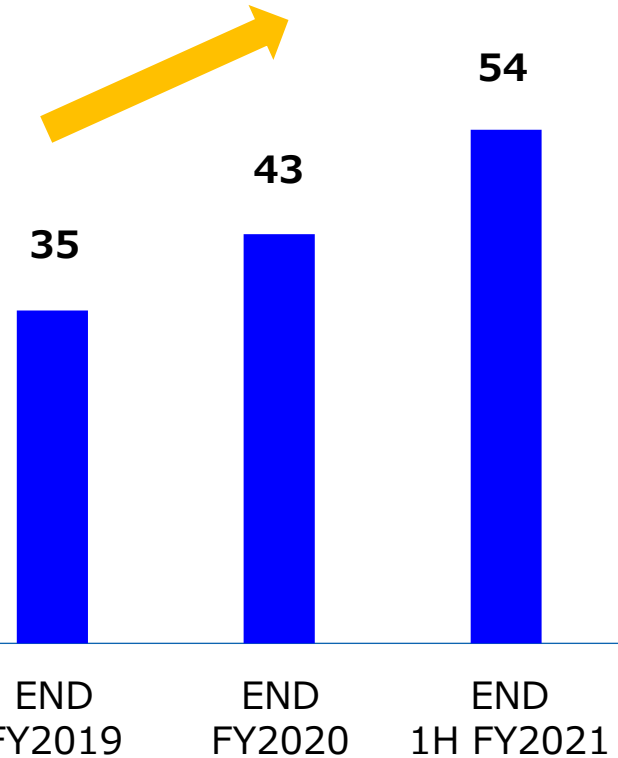


PROGRESS (2): GROWTH IN JAPAN BUSINESS (KPI)

ACCUMULATED NUMBER OF LUMIPULSE ANALYZERS
PLACED IN JAPAN MARKET



NUMBER OF LUMIPULSE MARKERS
INTRODUCED TO SRL



High growth of Lumipulse business in Japan is proof that
customers value Fujirebio's marker developed on Lumipulse

PROGRESS (3): NEURO/ALZHEIMER ROADMAP

Our Hypothesis

Automation of Cerebrospinal Fluid (CSF) markers

Demand for **Blood Based Markers** in addition to CSF Markers

Ultra High Sensitivity will be required for future Blood Based Markers

Key Initiatives

Based on **Innogenetics assets**, and global development project, Fujirebio launched CSF markers on Lumipulse

- Four CSF Markers on Lumipulse:
 - Amyloid Beta 1-42
 - Amyloid Beta 1-40
 - pTau 181
 - Total Tau
- Registered/Under Registration in Europe, Japan, US and Asia

Develop **Lumipulse reagents** and launch quickly as **Research Use Only (RUO) status**

- 3 Markers on Lumipulse: To be launched March 2022
- +3~5 Markers (in addition): Preparing to start Development
- IVD registration will start in each market

Develop separate platform from Lumipulse and launch as RUO

- **Expect more than 10 fold improvement in sensitivity** compared to current Chemiluminescence technology
- RUO launch in FY2023
- IVD registration will be planned as clinical data is collected

SUMMARY

- **FUJIREBIO transformed its Global Strategy in 2020, with trend in global diagnostic market**
 - **Continuous investment in R&D activities** is critical to develop unique markers on Lumipulse platform
 - Japan business, as H.U. Group, important to **prove value of new markers developed** on Lumipulse/Espline
 - **Focus on up-stream Development and Production activities** to approach Outside Japan Market
 - **Expand CDMO (Reagent OEM) Partnerships**
- **Key achievements observed through new strategic direction. Global organization is working effectively.**
 - 1) **Increase in CDMO projects:** Both “# of Partners” and “# of Development Projects (Accumulated)”
 - 2) **Growth in Japan Business:** Both “# of Instrument Placements” and “# of Markers in SRL”
 - 3) **Neuro/Alzheimer Development Roadmap:** Projects on-going based on global storyline/roadmap
- **Through implementing above strategy, we are on track to achieve the Revenue/Operating Profit targets in H.U. Group mid-term (FY2020~FY2024).**
- **We aim to continuously grow Revenue in the mid-single digit level, as well as to achieve over 20% OP Margin beyond next mid-term.**

(BLANK)