

# 2nd Quarter of FY 2025 Financial Results Briefing

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November 20, 2024

Kazuhiro Hatano, Representative Director  
Linical Co., Ltd.

# Agenda

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1. Company Overview
2. Financial Results for the Six Months  
Ended September 30, 2024
3. Management Strategy

# Corporate Profile



- Company name Linical Co.,Ltd. (TSE Standard 2183)
- Head Office 1 -6 -1 Miyahara, Yodogawa-ku, Osaka
- Establishment June 7, 2005
- Representative Kazuhiro Hatano, Representative Director
- Capital Stock 214 million yen
- Business Description Clinical Research & Development (CRO) business and Contract Medical Affairs Business
- Number of Employees 711 (330 in Japan and 381 overseas) \* As of March 31, 2024
- History of establishment  
April 1, 2005: Yamanouchi Pharmaceutical Co., Ltd., and Fujisawa Pharmaceutical Co., Ltd., merged to form Astellas Pharma Inc.  
June 7, 2005: Linical was established centered on **members with experience in drug development at Fujisawa Pharmaceutical** aimed at the ideal Contract Research Organization (CRO) business originating in Osaka.

# Practice our business philosophy and help patients



## Management Philosophy

To promote the greater wellbeing of all our stakeholders – patients, business partners, shareholders, and employees – we strive constantly to offer **professional**, high-quality services to support all aspects of new drug development.

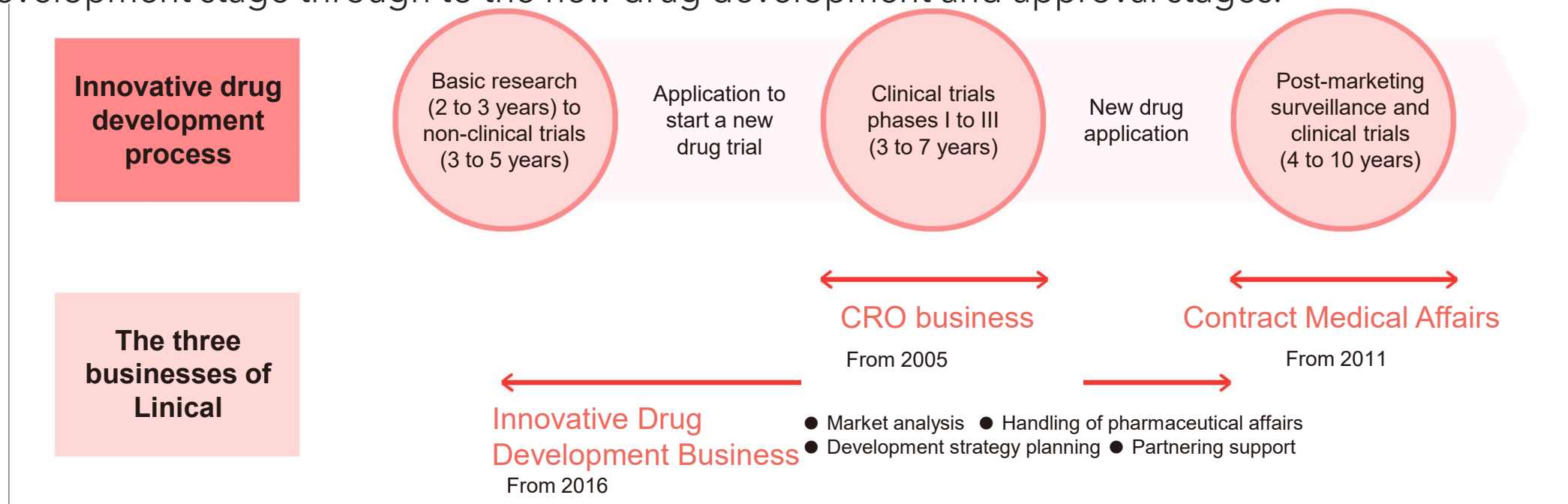


Blue: Integrity and Honesty  
Red: Unending enthusiasm  
Yellow: Continuing spirit of inquiry

Our corporate logo expresses **our passion to pursue happiness of patients** through our business activities.

# The Three Businesses of Linical

- We specialize in clinical development and cover the entire process from the innovative drug development stage through to the new drug development and approval stages.

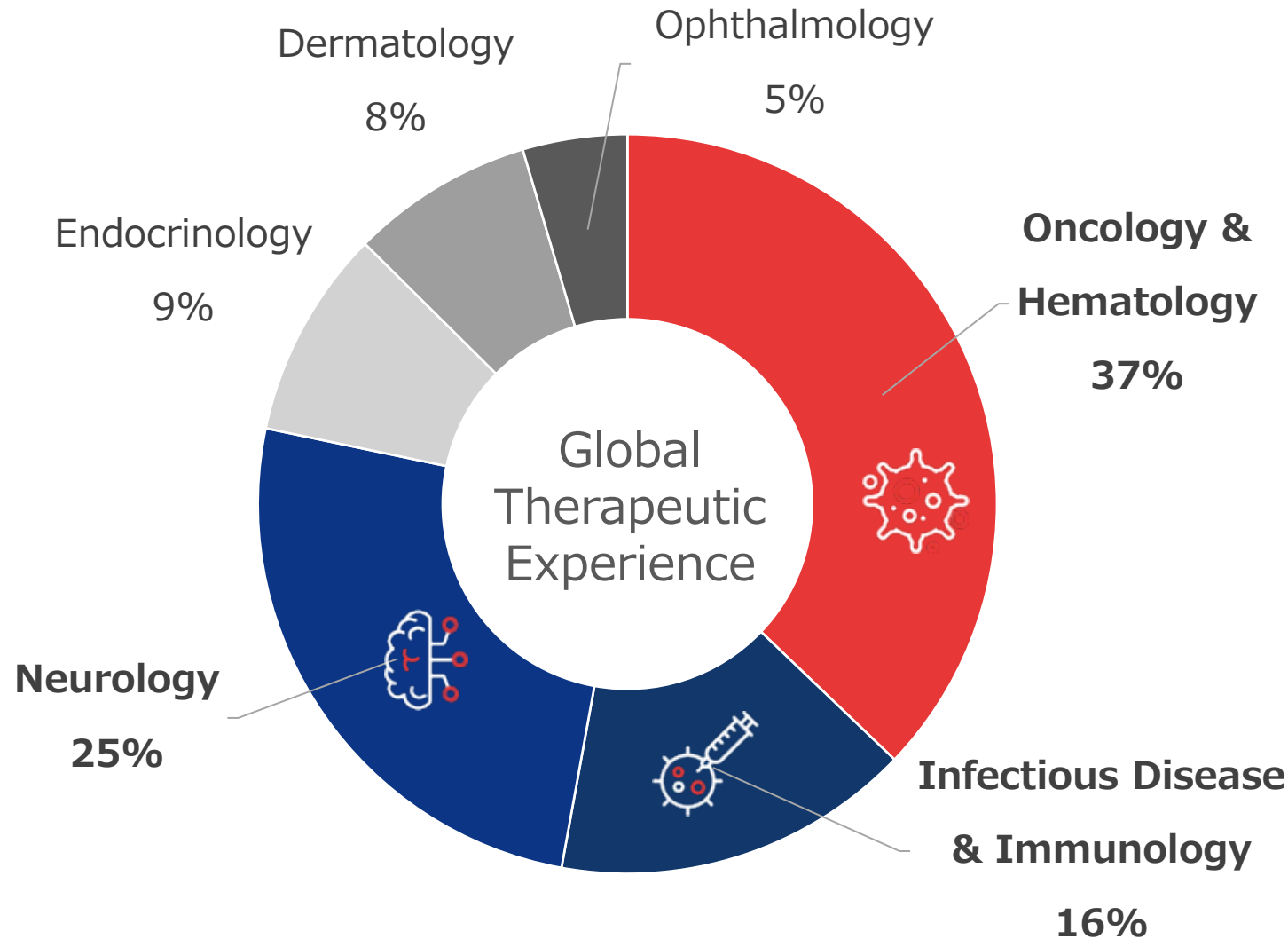


**1. CRO Business:** Implementing on client's behalf and supporting operations related to clinical trials conducted in the drug development stage

**2. Contract Medical Affairs business:** We support post-marketing clinical research and marketing activities

**3. Innovative Drug Development Business:** We provide consulting services that give total support for a wide range of pharmaceutical development activities including market analysis, the formulation of pharmaceutical affairs and development strategies, the selection of marketing partners, and the conclusion of contracts.

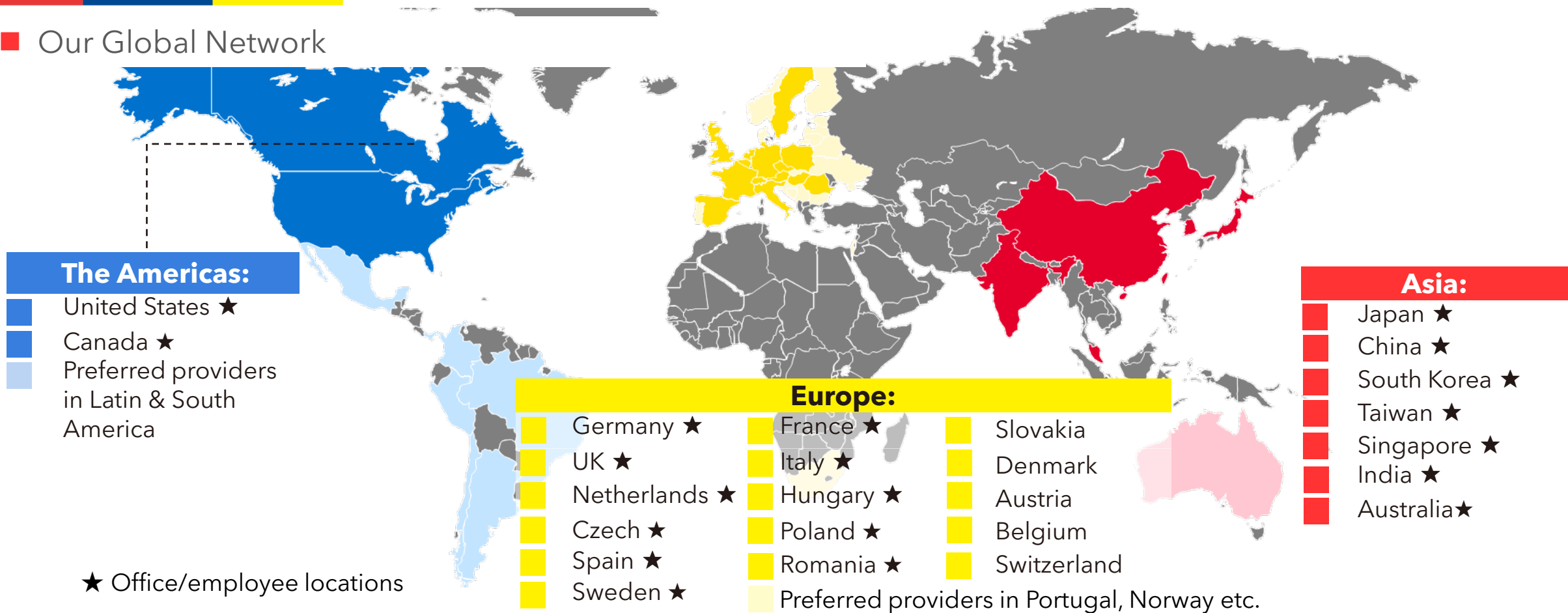
# Targeted Therapeutic Areas



Since our establishment, we have focused on the therapeutic areas of **oncology**, **neurology** and **immunology**, which have a high degree of difficulty and many unmet medical needs.

# Global CRO originating from Japan

■ Our Global Network



Currently has employees in about 20 countries/regions.  
Providing services in about 30 countries including affiliated partners



# Expansion of our Global Reach



## ■ New Jersey Office

- New office near New York to strengthen sales activities
- Established As of July 1, 2024



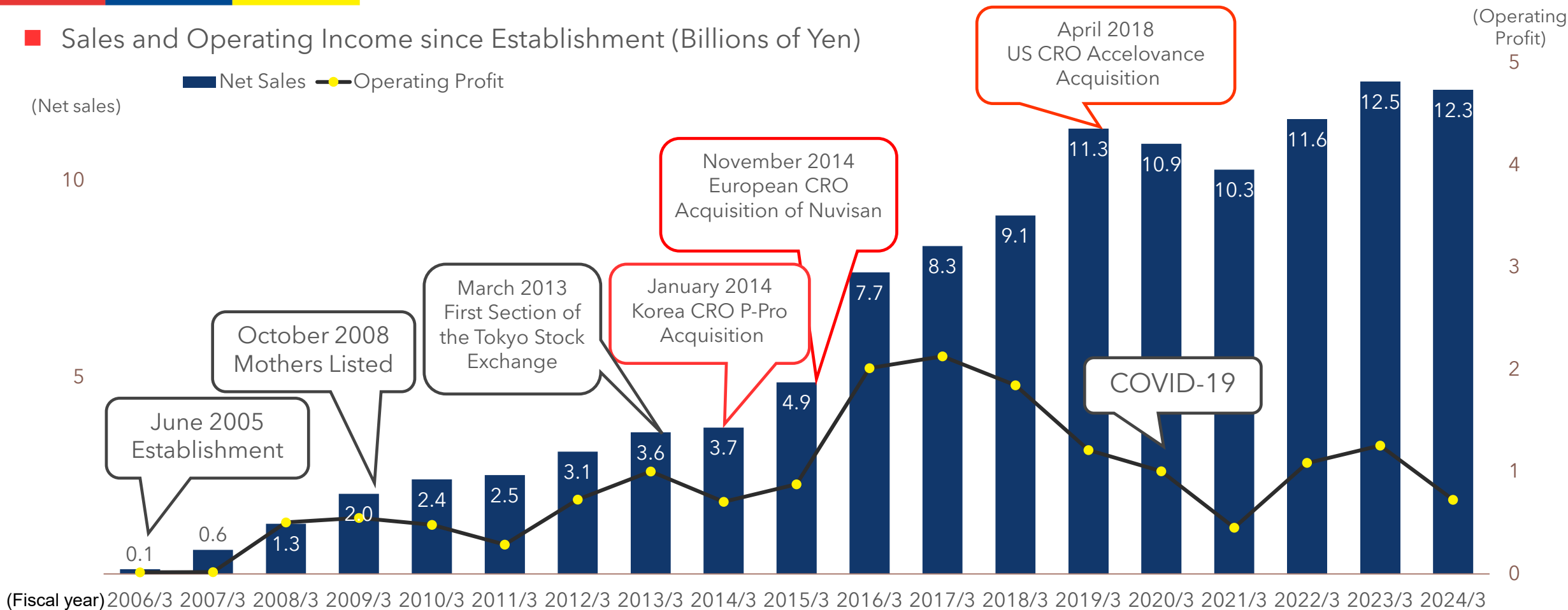
## ■ Linical Australia

- First affiliate in the Southern Hemisphere
- Established As of July 9, 2024





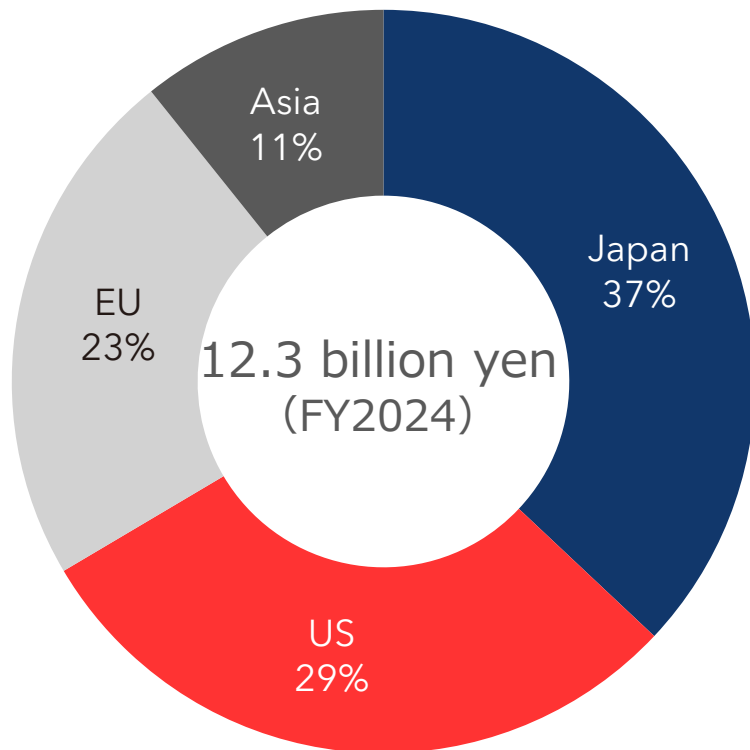
# Steady Growth through Overseas M&A



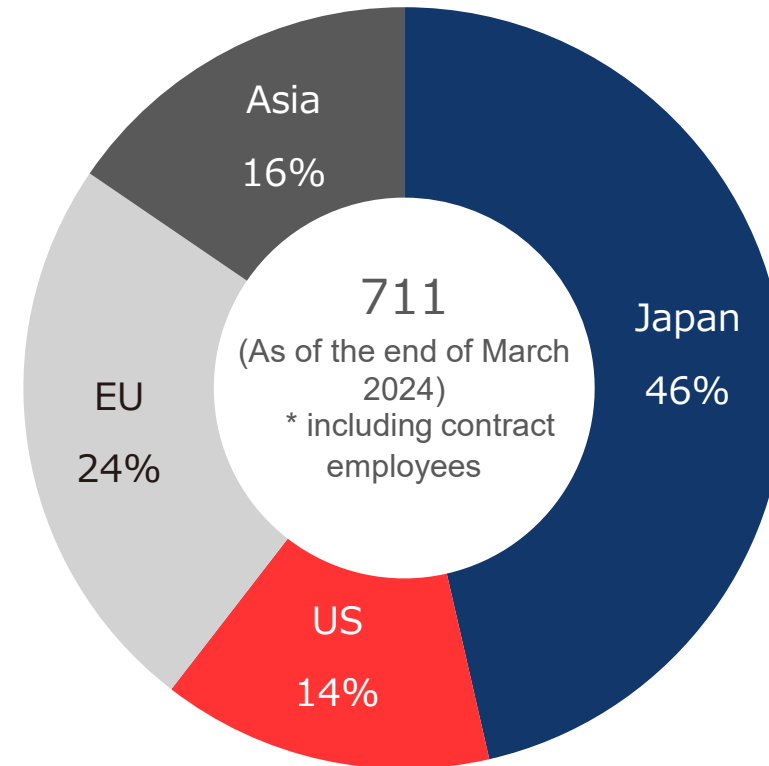
Growth centered on overseas business through M&As in South Korea, Europe, and the United States

# Sales and Employee Ratios by Region

■ Net Sales: Overseas ratio 63%



■ Number of employees: Overseas ratio 54%



Overseas ratio is more than 50% in terms of both sales and number of employees

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# Consolidated Financial Results

Units: millions of yen, %	Results for the Six Months Ended September 30, 2023		Results for the Six Months Ended September 30, 2024		
	Amount	Sales Ratio	Amount	Sales Ratio	Year-on-Year
Net Sales	6,064	100.0%	5,426	100.0%	△10.5%
Cost of Sales	4,079	67.3%	4,111	75.8%	0.8%
SG&A Expenses	1,563	25.8%	1,507	27.8%	△3.6%
Operating Profit	421	6.9%	△192	△3.6%	—
Ordinary Profit	483	8.0%	△239	△4.4%	—
Net Profit	178	3.0%	△280	△5.2%	—

■ Net sales:  
Consolidated net sales fell year-on-year, as sales in the United States increased significantly, but sales in other regions decreased.

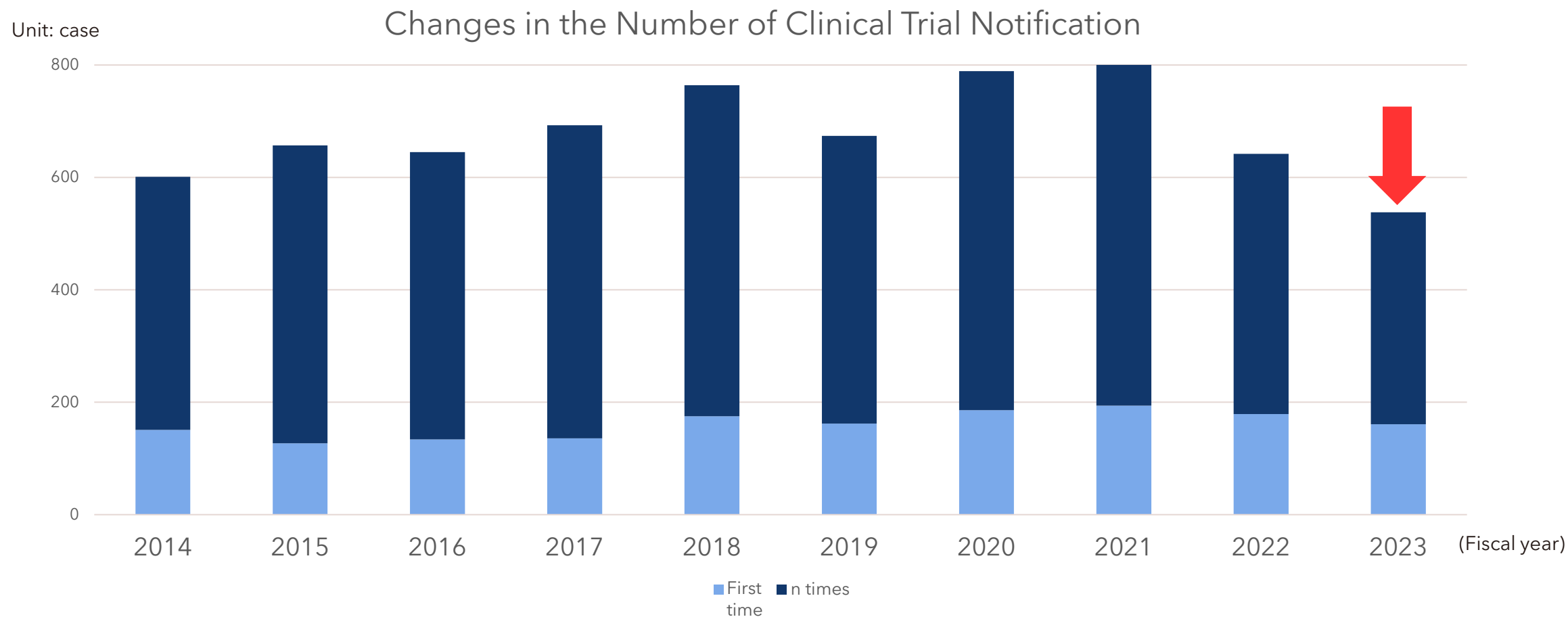
■ Operating profit:  
Profit on a consolidated basis also decreased year-on-year, as profit in the United States increased significantly, but other regions posted an operating loss.

# Financial Results by Region

Unit: Millions of yen	Results for the Six Months Ended September 30, 2023			Results for the Six Months Ended September 30, 2024					
	Net Sales **	Operating Profit	Ordinary Profit	Net Sales	Rate of Change %	Operating Profit	Rate of Change %	Ordinary Profit	Rate of Change %
Japan	2,682	370	478	1,892	△29.5	△215	—	△230	—
United States	1,998	304	308	2,513	25.8	410	34.9	431	40.2
Europe	1,578	△118	△147	1,565	△0.8	△54	—	△102	—
Korea	442	14	11	375	△15.1	△73	—	△80	—
Taiwan	50	△16	△16	42	△15.8	△28	—	△25	—
China	165	1	△5	115	△30.5	△7	—	△4	—
Consolidation Adjustments*	△853	△134	△146	△1,077	—	△223	—	△227	—
Total	6,064	421	483	5,426	△10.5	△192	—	△239	—

\* Amortization of goodwill is included in consolidation adjustments. \*\* Net sales have calculated before deducting internal transactions.

# Japan: Market environment remains challenging



The number of Clinical Trial Notification in FY2023 fell to the lowest level in the past 10 years

# South Korea: Prolonged confusion at medical sites

February: South Korean government expanded admission capacity at university medical schools as a measure to address the shortage of doctors  
Many doctors protested  
More than 1,000 young doctors went on strike, and nearly 6,500 interns and residents submitted resignations

Source: BBC News Japan, "[South Korean doctors strike in protest of plans to add more physicians](#)"

March: The strike expanded. More than 10,000 people (as of March) left their jobs.

Source: Asahi Shimbun Digital, "[Prolonged conflict between South Korean government and doctors led to some court battles](#)"

June: "Mass closures" at approximately 5,000 medical facilities nationwide, the largest such closure in Korea

Source: Asahi Shimbun Digital,  
"[Doctors and government at loggerheads, leaving patients behind, South Korea goes on prolonged strike over admission capacity increase at medical schools](#)"

The situation at large hospitals in the metropolitan area that many of the people were affiliated with was so serious that their mass departure caused **delays in medical treatment and surgery, as well as a string of partial hospital closures, and even the death of an emergency patient who was passed around because no hospital could be found for them**

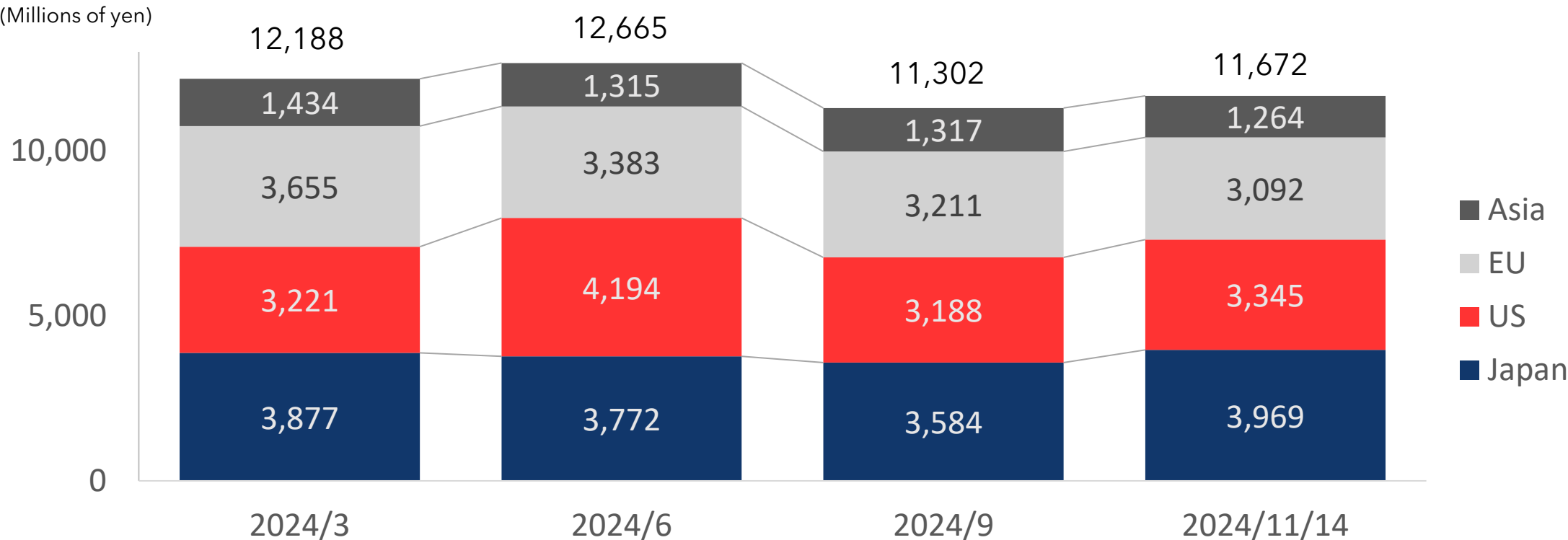
Source: Institute of Developing Economies  
"[Why did people leave their workplaces? - The problem of medical care in Korea as seen in the plan to increase admission capacity at medical schools](#)"

The confusion is still ongoing. It has exerted a significant impact on clinical trials.



# Hard Backlog by Region

\* Hard backlog:  
The balance of the amount for orders for contract business already concluded.  
This is an indicator that shows the amount of sales to be generated over the next one to five years and serves as the basis for the group's future results forecasts.



- Order (hard) backlog as of November 14, 2024, was worth 11.6 billion yen, down 4.2% from the end of March 2024
- Some of the contracts have not yet been signed, and the number is beginning to increase

# Hard Backlog by Region

## ■ Japan/Asia:

- Japan continues to face difficult market conditions, but the order backlog as of November 14 already exceeds that at the end of March 2024
- In South Korea, we had difficulties in getting new orders due to the medical strike. There are concerns that, if prolonged, it will have a greater impact on the Company
- We persistently continue marketing activities such as proposing entry into the Japanese and Asian markets to overseas biotech companies in cooperation with subsidiaries in Europe and the United States

## ■ United States:

- The order backlog increased compared with the end of March 2024 due to the winning of new projects and changes in contracts for existing projects to increase person-hours
- We see lots of inquiries from biotech companies and will continue sales efforts to increase orders

## ■ Europe:

- Synergies from the unification of management in Europe and the United States has led to increased new orders
- We enhance sales personnel and increase new orders, including in Europe

# Full-Year Forecast

	FY ended March 2024		FY ending March 2025 Previous Forecasts			FY ending March 2025 Latest Forecasts		
	Amount	Sales Ratio	Amount	Sales Ratio	Rate of Change	Amount	Sales Ratio	Rate of Change
Net Sales	12,307	100.0	12,669	100.0	2.9	11,468	100.0	△6.8
Operating Profit	725	5.9	1,009	8.0	39.0	250	2.2	△65.6
Ordinary Profit	790	6.4	1,047	8.3	32.5	258	2.2	△67.3
Net Profit	338	2.7	697	5.5	106.1	150	1.3	△55.7

We revised full-year forecasts in light of conditions through the first half of the fiscal year

# Balance of Goodwill and Remaining Amortization Period (As of March 2024)



Unit: Millions of yen	Goodwill			Related intangible assets other than goodwill *2		
	Balance at End of Term	Remaining Amortization Period(year)	Annual Amortization *3	Balance at End of Term	Remaining Amortization Period(year)	Annual Amortization *3
KOREA	Termination of depreciation in FY 2019			Termination of depreciation in FY 2019		
EUROPE *1	1,355	9-10年	148	9 67	3年 6.7年	3 10
USA *1	2,192	10年	217	34	3年	11
TOTAL	3,547	—	365	111	—	24

Approximately 0.39 billion yen is recorded every fiscal year as amortization expenses related to past mergers and acquisitions

\*1 Goodwill generated by the acquisition of Linical Accelovance America, Inc., has been apportioned pro rata to its European subsidiary.

\*2 Intangible assets other than goodwill recognized by purchase price allocation.

\*3 Figures have been converted at the exchange rate as of the end of the fiscal year ended March 2024.

# Agenda

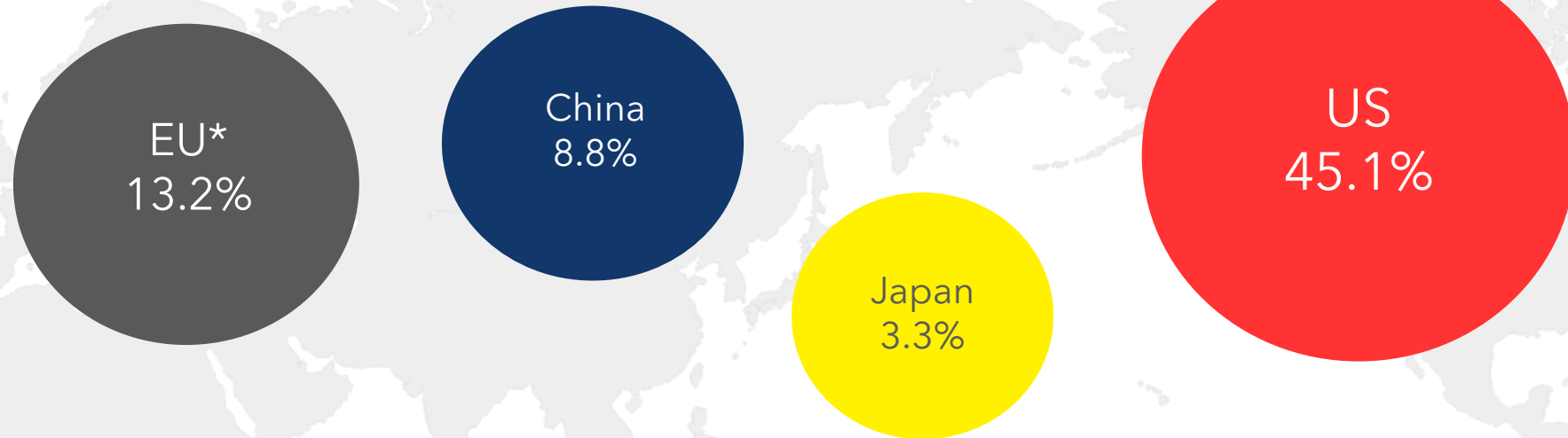
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# Global pharmaceutical market size in 2028

■ Regional share of global market in 2028



**Worldwide: USD 1,607 bil (2023) - > 2,238 bil (2028)**

Through 2028, the global pharmaceutical market is projected to grow at a compound annual growth rate of 6 - 9%.

**It is essential to expand our business in the United States, the largest market.**

# Medium to long-term goal

## ■ Number of employees

More than

Global 1,500 people

As of the end of March 2024

711 people

## ■ Number of countries where we do business

As of the end of March 2024

60 countries

About 20 countries

EU:

400



Asia:

400



Japan:

500



US: Most Important

400



As of the end  
of March 2023

171



110



330



100



- Targets [1] 500 people in Japan, 400 people in Asia, 400 people in Europe, 400 people in the US  
=> Building of a framework with more than 1,500 people
- [2] Maintenance of profitability and improvement of profit margins while investing in growth (including M&A) in each region
- [3] Expansion into about 60 countries worldwide



# Initiatives for the Strengthening of Profitability

## Key Issues for Sustainable Sales Growth and Increased Profitability

### 01 Growth of Overseas Business

We expand our service network around the world, with a focus on the United States, the most important market

### 02 Expansion of Customer Base

We expand our customer base from major domestic pharmaceuticals to overseas pharmaceutical and biotech companies

### 03 Expansion of Disease Areas

In addition to the three focus areas, we expand into ophthalmology and dermatology, where needs are increasing due to the aging society, and into new modalities of regenerative medicine and SaMD (Service as Medical Device)

### 04 Enhancement of service coverage

We enhance full-service capabilities from the drug discovery phase through all phases of clinical trials

We continue to take on the challenge of new treatment methods, such as regenerative medicine and apps, in light of **changes in the market environment**

# 01 Growth of Overseas Business

## We expand our service network around the world, with a focus on the United States, the most important market

### United States

We are accelerating our plan to increase personnel and promptly realize M&As

### Europe

We unified management with the United States to reinforce our presence in major European countries  
We established a development system in the Scandinavian Peninsula (Sweden), an area we had not yet entered into

### Asia-Pacific

We established an office in Australia  
We intend to attract FIH (First In Human) trials by biotech companies in Europe and the United States, and to be commissioned to conduct international collaborative trials in the next phase and beyond

### Australia's clinical trial environment

1. Very fast turnaround time from clinical trial application to start
2. Multiple world-class Phase I study centers
3. Tax incentives for pharmaceutical and biotech companies conducting clinical trials in the country

In many cases, biotech companies in Europe and the United States conduct a Phase I study in Australia, followed by Phase II and III studies in Europe and the United States

## 02 Expansion of Customer Base

### Expand our customer base from major domestic pharmaceuticals to overseas pharmaceutical and biotech companies

#### **Emerging biopharma companies in Europe and the United States: Main player in drug discovery and priority target**

We expanded transactions in line with business growth in Europe and the United States. Repeating customers include some that have grown significantly from ventures.

We are also working to attract them to the Japanese market, and are strengthening collaboration and activities between the innovative drug developments at the Japan headquarters and sales teams in Europe and the United States

#### **Major pharmaceutical companies outside of Japan**

We strengthen the European and United States sales team structure to win orders for early-stage and real-world testing

#### **Japanese medium-sized pharmaceutical companies**

We see an increased interest in the Chinese market, so we stepped up our marketing activities

#### **Innovative Drug Development Business: Entrance to Japan**



We are increasing our consulting experience with overseas customers across a wide range of disease areas and product types

# 03 Expansion of Disease Areas

**In addition to the three focus areas, we are expanding into ophthalmology and dermatology, where needs are increasing due to the aging society, and into new modalities such as regenerative medicine and SaMD**

## **We have focused on oncology, neurology, and immunology since our founding**

Awarded projects are increasing in the oncology field at overseas subsidiaries. CNS is strong in Japan and Asia.  
Orders are stable in autoimmune and rare disease areas

## **Strengthening of ophthalmology and dermatology areas where needs are increasing in an aging society**

We won ophthalmology and dermatology projects in Japan and Asia

## **Approach to new drug discovery modalities**

Inquiries about regenerative medicine and therapeutic applications/digital medical devices are increasing, and in addition to the innovative drug development business, steady progress is being made in clinical trials under contract

### **We are providing comprehensive support for Heartseed's domestic Phase I/II clinical trials**

Biotechnology venture founded by Keiichi Fukuda, Professor Emeritus of Keio University

They established "cardiac regenerative medicine," a therapy that transplants microtissues (cardiomyocytes) derived from allogeneic iPS cells into the heart, and are developing HS-001 to contribute to treatment for patients with severe heart failure

# 04 Enhancement of service coverage



## We enhance full-service capabilities from the drug discovery phase through all phases of clinical trials

### **Innovative Drug Development Business**

Consultation projects for the transition from non-clinical to clinical trials increased. We plan to increase personnel

### **Data management and statistical analysis**

We strengthen recruitment and training of personnel in data management and statistical analysis in the United States, Japan, and South Korea, which are important for planning clinical trials

### **We expand collaboration with other companies for functions that we do not have**

We collaborate with external experts to strengthen CMC (chemistry, manufacturing, and control) development support and regulatory affairs consulting functions for regenerative medicine and other products, in addition to building a network of system partners required for Decentralized Clinical Trials (DCT) and other activities

# The way we want to be



## To be the “Strongest” CRO

We are aiming to be the strongest CRO, not the biggest. To be the strongest CRO, we need to be **knowledge-intensive** rather than labor-intensive, and to achieve the highest profitability in the industry. To realize this, each team member will aim to **outperform the competition in terms of revenue per person**



# Cautionary Notes

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