

# The Fiscal Year Ended March 31, 2024

# Consolidated Financial Results Briefing

Presentation Material

**May 8, 2024**



株式会社新日本科学

SHIN NIPPON BIOMEDICAL LABORATORIES, LTD.



<b>1. FY3/24 Overview &amp; Future Outlook</b>	<b>P. 3</b>
<b>2. Outline of FY3/24 Consolidated Financial Results</b>	<b>P. 12</b>
<b>3. Business Topics</b>	
<b>I. CRO (Nonclinical)</b>	<b>P. 26</b>
<b>II. CRO (Clinical)</b>	<b>P. 38</b>
<b>III. TR</b>	<b>P. 40</b>
<b>IV. Medipolis</b>	<b>P. 48</b>
<b>4. Q&amp;A</b>	

# 1. FY3/24 Overview & Future Outlook

---



Ryoichi Nagata, MD, PhD, FFPM  
Representative Chairman and President

## 1. FY3/24 Financial Results

- Record-high revenue achieved for the 2nd consecutive year, while profits decreased mainly due to costs related to Satsuma Pharmaceuticals, which was acquired last year (¥1.34B).
- Contracts received in nonclinical business increased by 10% YoY, marking the highest records for both contracts received and backlog.
- Record-high equity method profit of ¥2.63B (up by 33.8% YoY) from PPD-SNBL posted.
- Plan to continue distributing the highest-ever full-year dividend of ¥50/share for FY3/24.

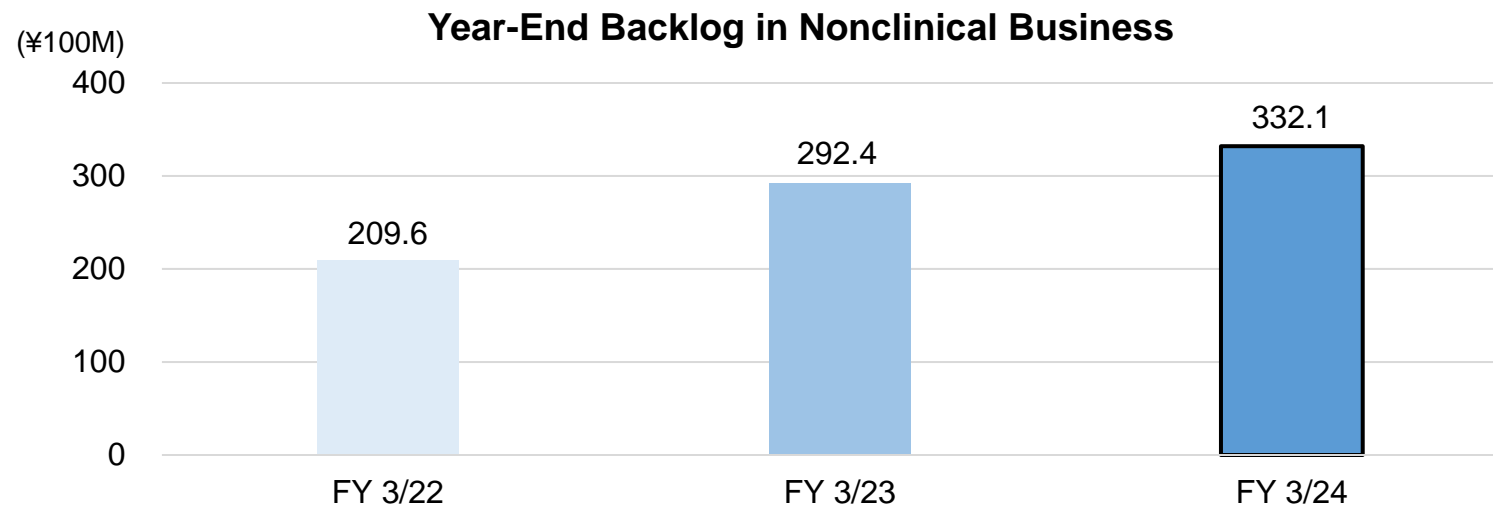
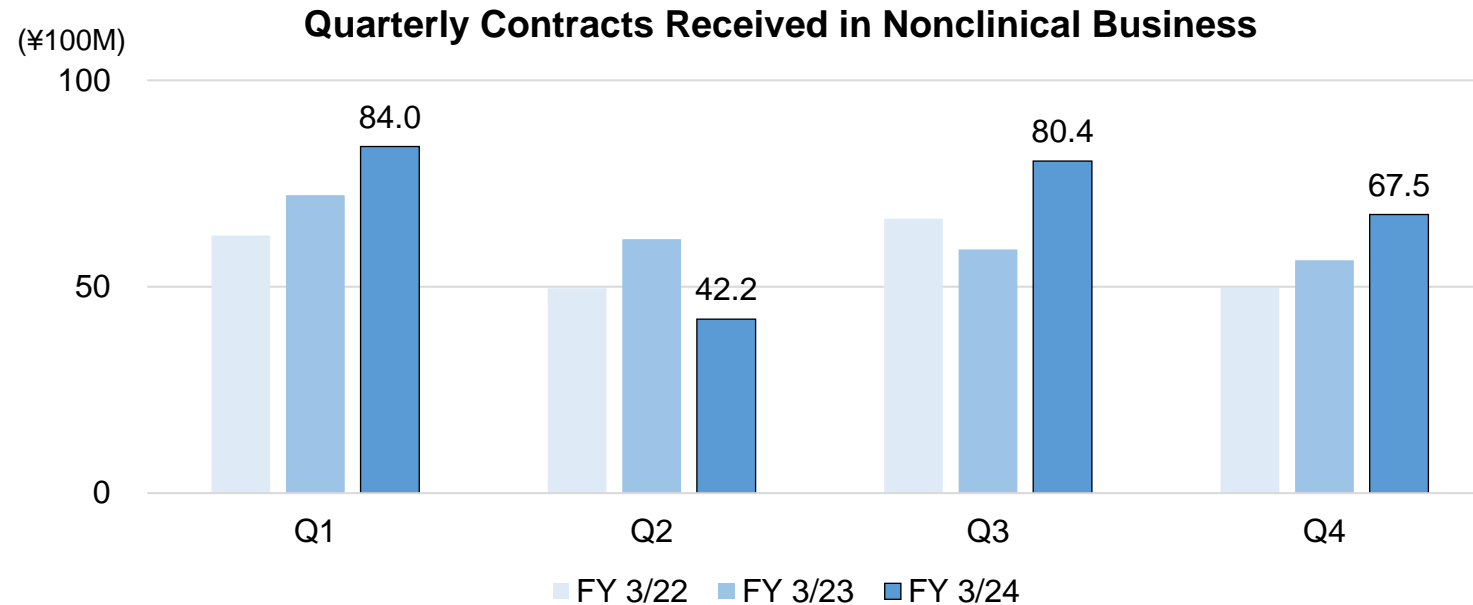
## 2. FY3/25 Forecast & Future Outlook

- Decrease in profits expected mainly due to costs related to applying for FDA approval of Satsuma's intranasal migraine drug, STS101 (¥3.29B).
- Contracts received in nonclinical business expected to increase to ¥34.2B, (up by 25% YoY).
- Strategic up-front investment for SNBL's sustainable growth will continue in FY3/25. We expect to enter a return on investment phase from FY3/26 and onwards.

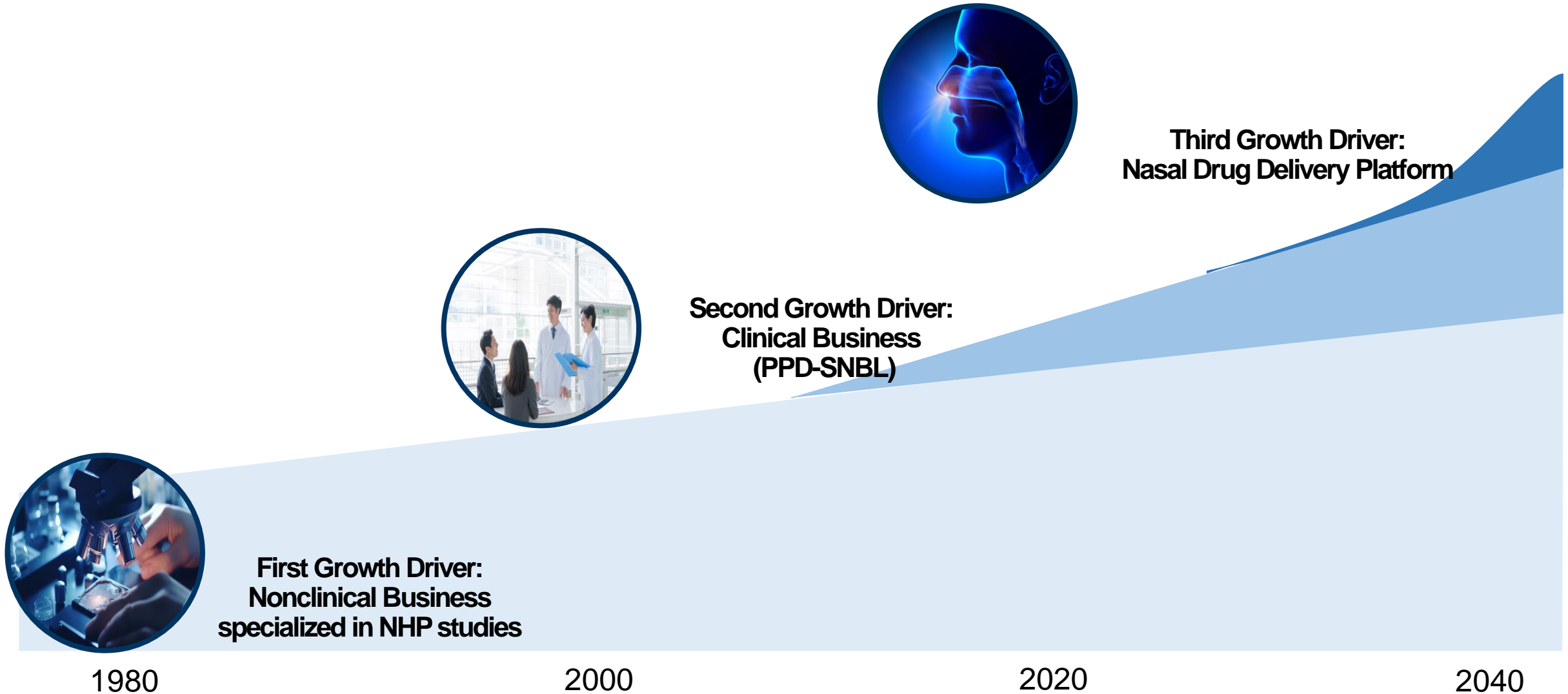
## 3. Enhancing Corporate Value Through Human Capital Management

- Initiatives for human capital management: promote businesses based on SNBL's corporate management concept of "encouraging employees' growth".
- Introduced a new work style system aiming to build "a company where everybody works happily."

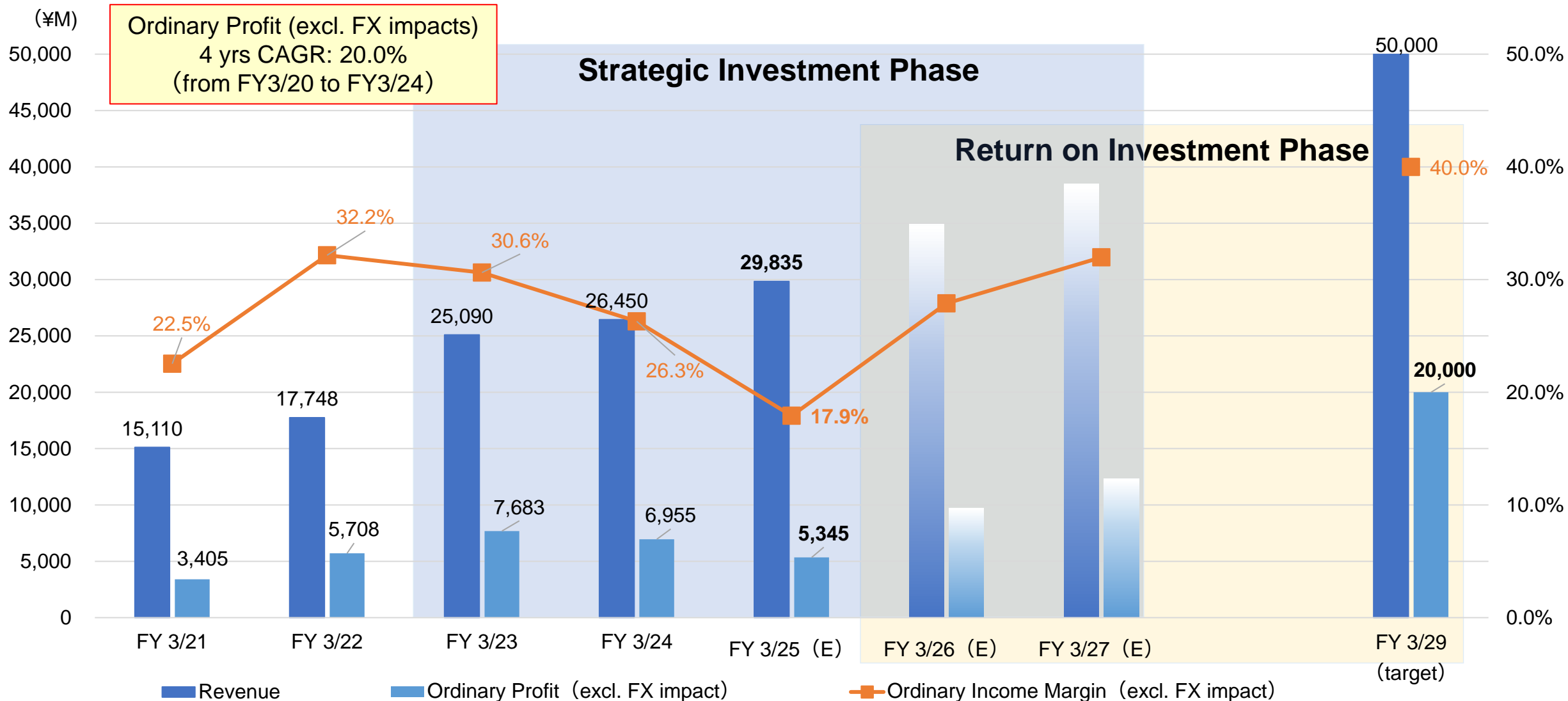
# Contracts Received and Backlog in Nonclinical Business



# Powering Three Drivers for Sustainable Growth



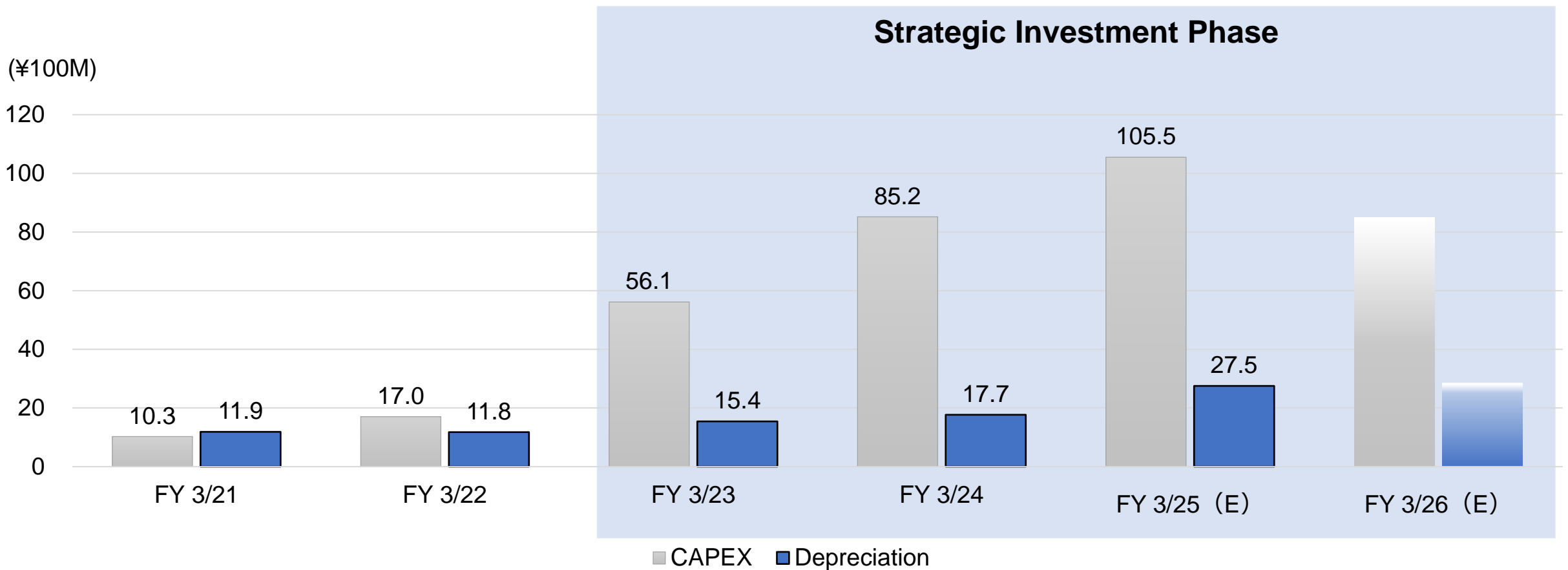
# Conceptual Image of Strategic Investment and Its Return



# Capex Plans to Reach Peak in FY3/25



Our large up-front investments in facility expansion and establishment of a domestic NHP breeding system are planned to reach their peak in FY3/25.

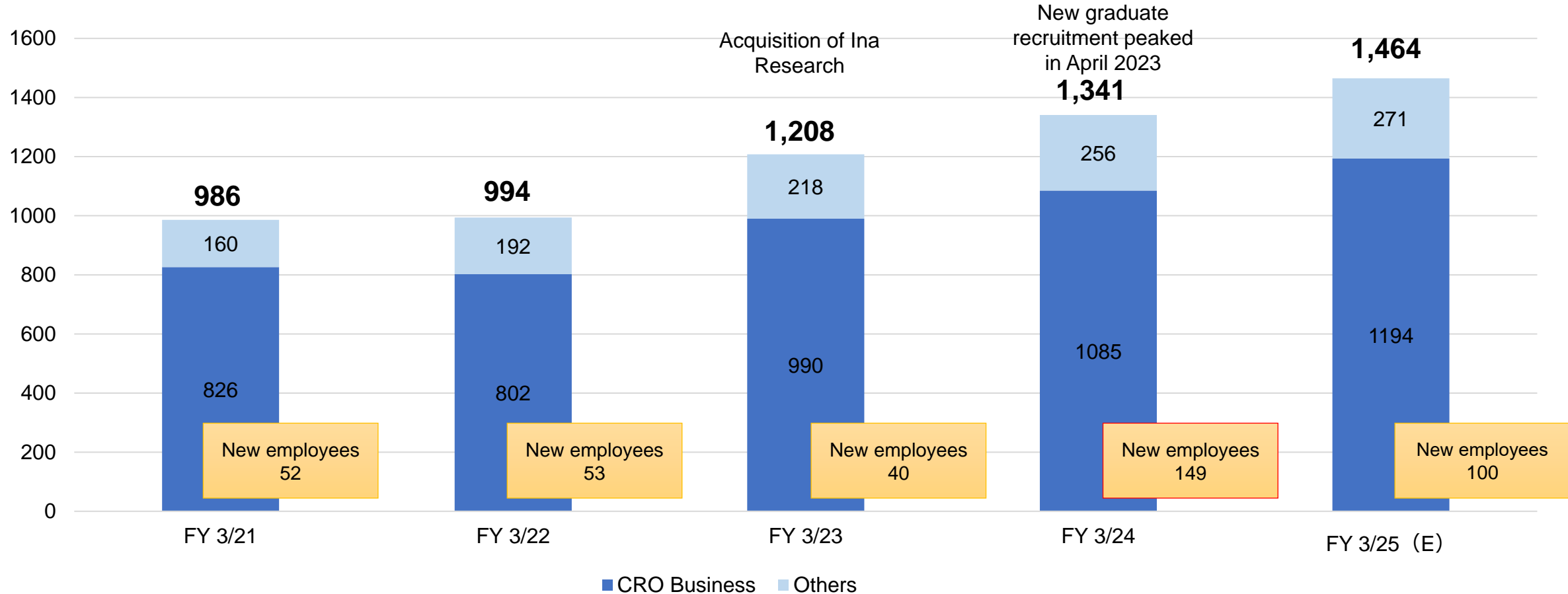




# Significant Enhancement of Human Capital



## Number of Employees

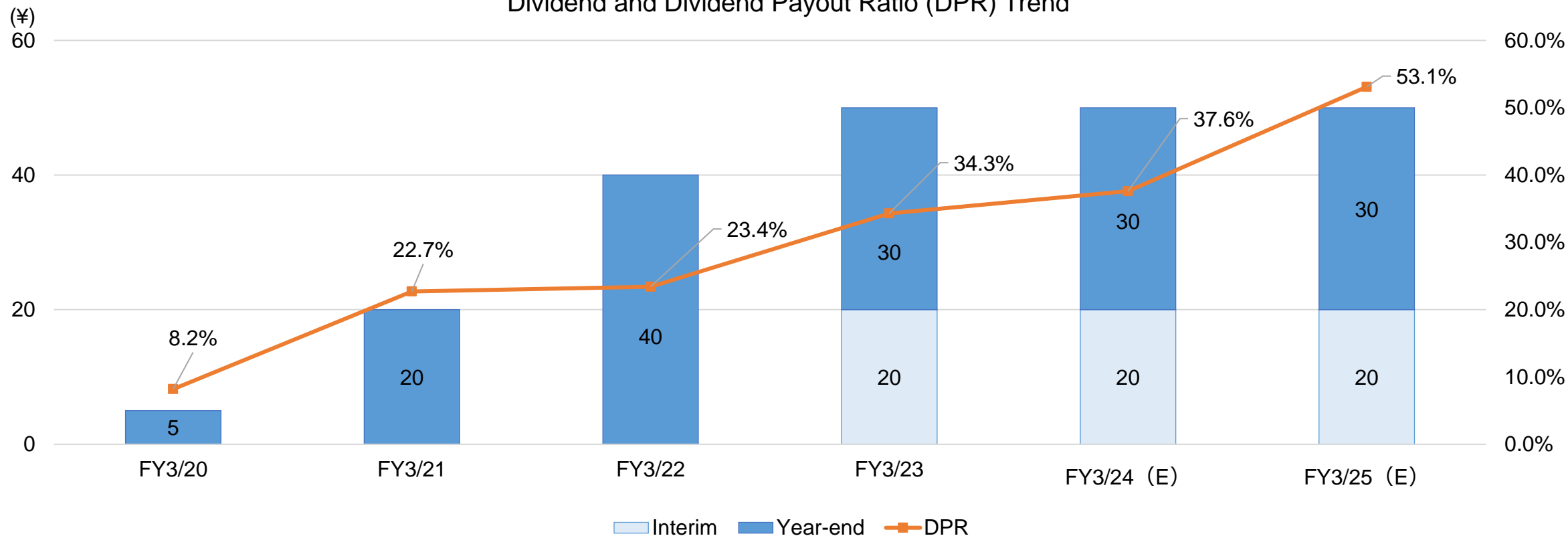


Number of employees does not include part-time or temporary employees.

# Shareholders Return



Dividend and Dividend Payout Ratio (DPR) Trend

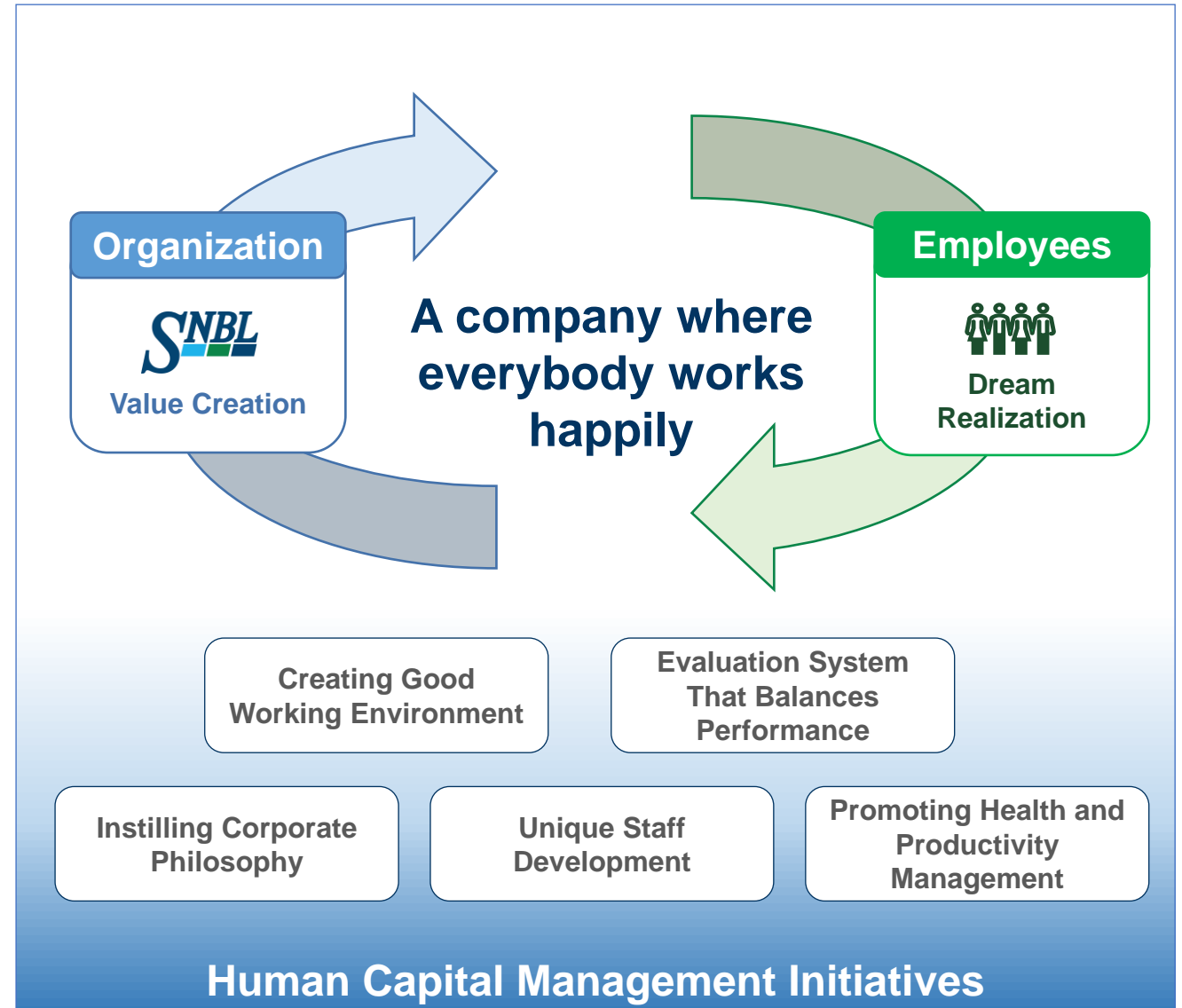


	FY3/20	FY3/21	FY3/22	FY3/23	FY3/24 (E)	FY3/25 (E)
Dividend per share	¥ 5/share	¥ 20/share	¥ 40/share	¥ 50/share	<b>¥ 50/share</b>	<b>¥ 50/share</b>
<b>Dividend payout ratio</b>	8.2%	22.7%	23.4%	34.3%	37.6%	53.1%

# SNBL's Human Capital Management Initiatives



- The seventh company listed on the Tokyo Stock Exchange to receive the “Platinum Eruboshi” certification for proactively promoting women’s engagement in the company
- Newly created **Childcare Support System**
- Introduced **new work style system**
- Recognized as one of the “White 500” Certified Health & Productivity Management Outstanding Organizations for the eighth consecutive year
- Construction of new HQ and research buildings in Kagoshima to be completed this month (i.e. May 2024)



# Outline of FY3/24 Consolidated Financial Results

---



Toshiyuki Iwata,  
Executive Officer in charge of Sustainability  
Head of IR and Corporate Communications

# Our Businesses Extend Across Drug Development Phases



## ■ Company Overview

Name: Shin Nippon Biomedical Laboratories, Ltd. (TSE Prime, ticker code 2395)

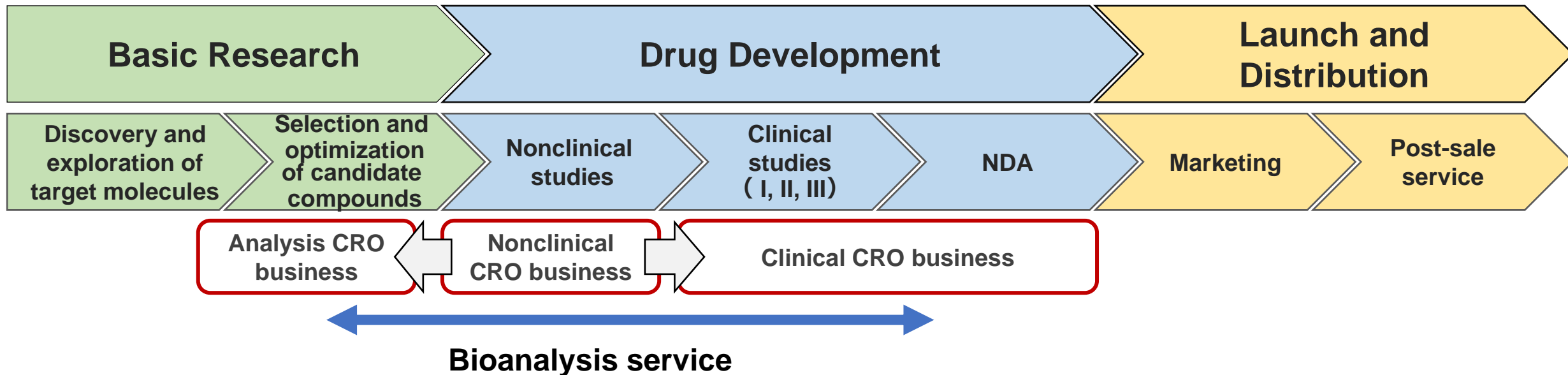
Foundation: September 16, 1957 (Incorporation: May 1973)

HQ location: Kagoshima City, Kagoshima Pref.

Main business: Contract Research Organization (CRO) business

Number of employees: 1,341 Female ratio: 51.6% (as of 31/3/2024)

## ■ Drug Development Phases and Expansion of SNBL's Business Domain



# FY3/24 Consolidated Financial Results Highlights



- Revenue and profits all exceeded the forecast announced on Feb. 2, 2024 and record-high revenue achieved for the 2nd consecutive year.
- Ordinary profit decreased by ¥1.08B mainly due to costs related to preparations for FDA approval of Satsuma's migraine drug candidate STS101(¥1.34B).

(¥100M)

	FY3/23	FY3/24					
		Previous Forecast (Feb. 2, /2024)	Results	Changes (Previous Forecast)		YoY Changes	
Revenue	250.9	261.9	264.5	+2.6	1.0%	+13.6	5.4%
Operating Profit	52.4	34.7	41.6	+6.9	20.0%	-10.8	-20.6%
Ordinary Profit	91.9	63.9	70.1	+6.2	9.8%	-21.8	-23.7%
Ordinary Profit (excl. FX impacts)	76.8	61.1	69.5	+8.4	13.8%	-7.3	-9.5%
Profit Attributable to Owners of Parent	60.6	39.7	55.3	+15.6	39.2%	-5.3	-8.7%

# FY3/24 Earnings Structure



## Earnings Structure FY3/24 (¥M)

	FY3/23	FY3/24	Increase
Revenue	25,090	26,450	1,360
Gross Profit	13,046	14,282	1,236
<b>GP Ratio</b>	<b>52.0%</b>	<b>54.0%</b>	
SGA Expenses	7,801	10,120	2,319
R&D	683	1,741	1,058
Breeding & Maintenance	871	1,333	462
<b>SGA/Revenue Ratio</b>	<b>31.1%</b>	<b>38.3%</b>	
Operating Profit	5,245	4,162	-1,083
<b>OP Ratio</b>	<b>20.9%</b>	<b>15.7%</b>	
Non-operating Income	4,241	3,254	
Share of profit of entities accounted for using equity method	2,489	2,751	
Of which, PPD-SNBL	1,967	2,632	665
FX Gains	1,511	60	-1,451
Non-operating Expenses	292	401	
Ordinary Profit	9,194	7,015	-2,179
<b>Ordinary Profit Ratio</b>	<b>36.6%</b>	<b>26.5%</b>	

GP ratio improved by 2.0% thanks to strong growth of contracts received and revenue in Nonclinical business, SNBL's prime source of earnings.

Operating profit decreased mainly due to posting of Satsuma-related costs(¥1.34B, of which ¥0.95B for R&D) and strategic up-front investments for significant increase of employees, lab facility expansion, and establishment of a domestic NHP breeding system.

Total personnel expenses, which is a sum of personnel expenses in SGA items and labor cost in cost of sales, increased by 15.3% (up by ¥1.4B YoY).

Ordinary profit decline was mainly due to a decrease in FX gains (-¥1.45B YoY). Share of profit of entities accounted for using equity method from PPD-SNBL increased (+ ¥0.66B YoY)

# Contracts Received and Backlog in Nonclinical Business



## Quarterly Contracts Received in Nonclinical Business

(¥M)

	FY3/22					FY3/23					FY3/24				
	Q1	Q2	Q3	Q4	Full-year	Q1	Q2	Q3	Q4	Full-year	Q1	Q2	Q3	Q4	Full-year
<b>Contracts Received</b>	6,242	4,965	6,652	4,979	<b>22,839</b>	7,219	6,153	5,905	5,642	<b>24,920</b>	8,398	4,217	8,044	6,752	<b>27,411</b>
Japan	4,593	3,854	4,232	3,638	<b>16,318</b>	3,887	3,754	3,726	4,971	<b>16,339</b>	6,208	3,471	5,051	5,628	<b>20,358</b>
Overseas	1,649	1,111	2,420	1,341	<b>6,521</b>	3,332	2,399	2,179	671	<b>8,581</b>	2,189	745	2,993	1,124	<b>7,051</b>
US & Europe	1,311	827	1,759	802	<b>4,699</b>	2,844	484	1,489	420	<b>5,237</b>	1,661	827	1,830	755	<b>5,073</b>
Asia	338	283	662	539	<b>1,822</b>	488	1,915	690	251	<b>3,344</b>	527	-81	1,162	368	<b>1,976</b>
Overseas Ratio	26.4%	22.4%	36.4%	26.9%	<b>28.6%</b>	46.2%	39.0%	36.9%	11.9%	<b>34.4%</b>	26.1%	17.7%	37.2%	16.6%	<b>25.7%</b>
<b>Cancellations</b>	-235	-196	-171	-435	<b>-1,038</b>	-549	-926	-1,414	-1,281	<b>-4,169</b>	-475	-1,559	-834	-1,110	<b>-3,978</b>
<b>Backlog</b>	17,216	17,671	19,960	20,966	<b>20,966</b>	25,756	33,672	32,585	29,248	<b>29,248</b>	33,329	32,210	33,863	33,212	<b>33,212</b>

Note) Ina Research is included from Q2 FY3/23 onwards. Cancellations are recorded as negative by date of occurrence.



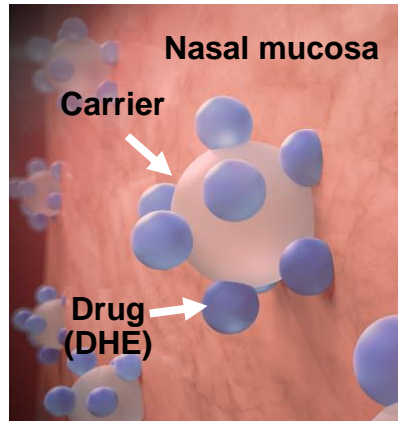
# Nasal Drug Delivery Platform Technology

SNBL - TR Business  
Proprietary Nasal Drug  
Delivery System

Nasal Drug  
Carrier

+

Nasal Delivery  
Device  
(medical device)



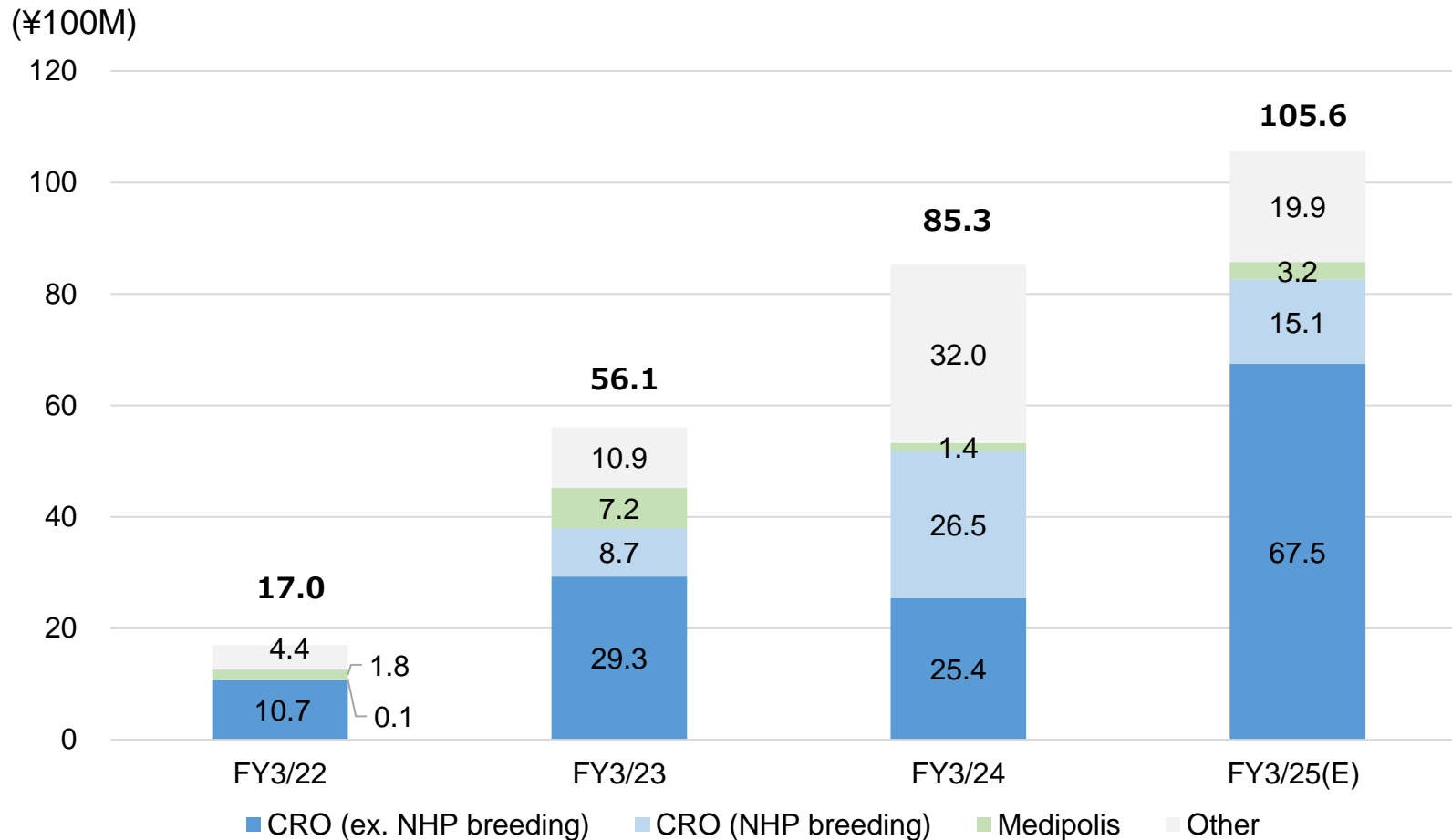
Unique muco-adhesive  
powder carrier

Nasal Delivery Drug  
as New Medicine



Patient-friendly, light-weighted and  
easy-to-use design

Large up-front investments in facility expansion and establishment of a domestic NHP breeding system is planned to reach the peak in FY3/25.

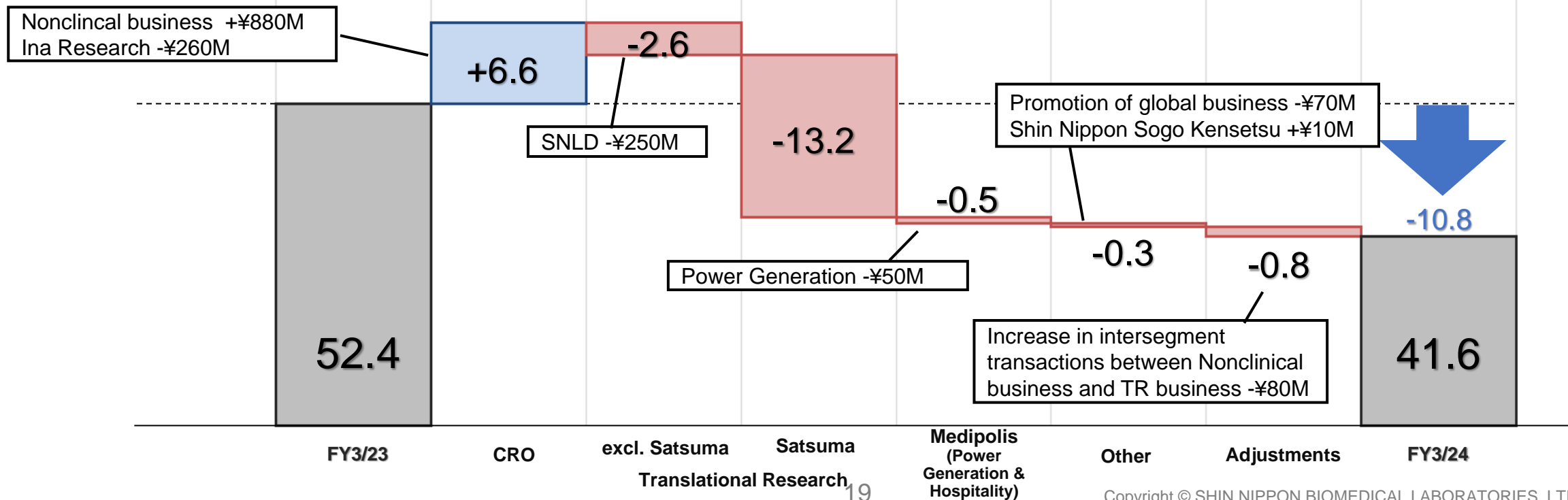


Perspective drawing of New HQ and Research Buildings construction will be completed around the end of May 2024.

# YoY Comparison of Consolidated Operating P/L FY3/24



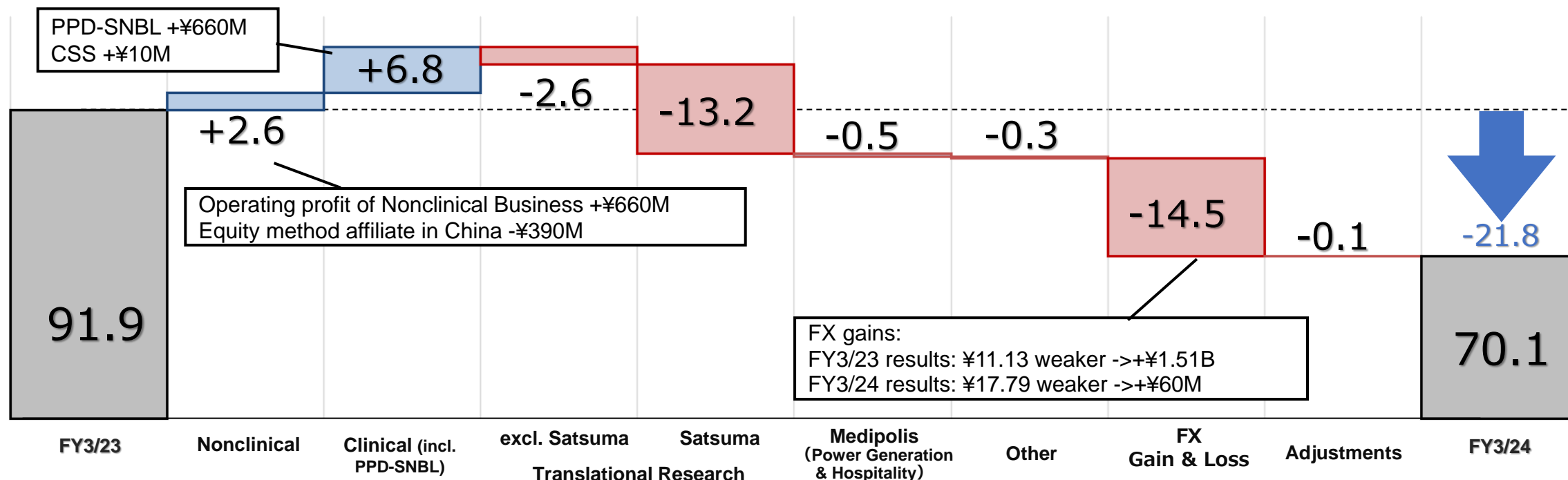
(¥100M)	CRO Business	Translational Research Business		Medipolis Business (Power Generation & Hospitality)	Other	Adjustments	Operating Profit Total
		excl. Satsuma	Satsuma				
<b>FY 3/24 Results</b>	<b>69.9</b>	<b>-11.3</b>	<b>-13.2</b>	<b>-2.5</b>	<b>0.8</b>	<b>-2.1</b>	<b>41.6</b>
FY 3/23 Results	63.3	-8.7	0.0	-2.0	1.1	-1.3	52.4
YoY Changes	+6.6	-2.6	-13.2	-0.5	-0.3	-0.8	-10.8



# YoY Comparison of Consolidated Ordinary P/L FY3/24



(¥100M)	CRO Business		Translational Research Business		Medipolis Business (Power Generation & Hospitality)	Other	Foreign Exchange Gain & Loss	Adjustments	Ordinary Profit Total
	Nonclinical	Clinical (incl. PPD-SNBL)	excl. Satsuma	Satsuma					
<b>FY 3/24 Results</b>	<b>71.4</b>	<b>27.9</b>	<b>-11.3</b>	<b>-13.2</b>	<b>-2.5</b>	<b>0.8</b>	<b>0.6</b>	<b>-3.6</b>	<b>70.1</b>
FY 3/23 Results	68.8	21.1	-8.7	0.0	-2.0	1.1	15.1	-3.5	91.9
YoY Changes	+2.6	+6.8	-2.6	-13.2	-0.5	-0.3	-14.5	-0.1	-21.8



# FY3/25 Financial Forecast

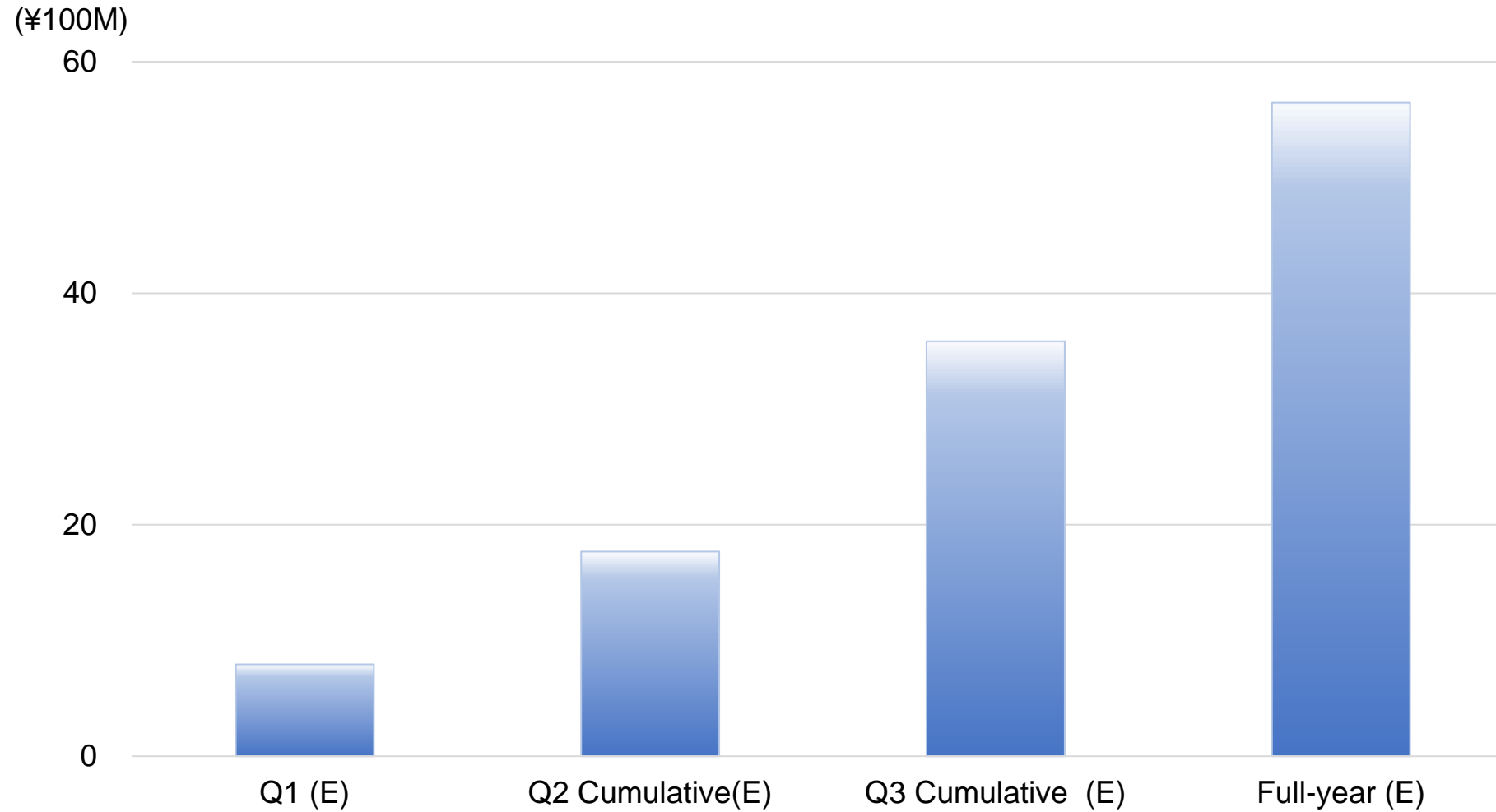


- Record-high revenue, up by 12.8% YoY, expected for the 3<sup>rd</sup> consecutive year.
- Decrease of ¥1.81B in operating profit foreseen mainly due to costs related to Satsuma Pharmaceutical's intranasal migraine drug STS101 for FDA approval(¥3.29B, up by ¥1.95B YoY).

(¥100M)	FY3/24	FY3/25		
		Full-year Forecast	YoY Changes	
Revenue	264.5	298.3	+33.8	12.8%
Operating Profit	41.6	23.5	-18.1	-43.5%
Ordinary Profit	70.1	53.4	-16.7	-23.8%
Profit Attributable to Owners of Parent	55.3	39.2	-16.1	-29.1%

Business Profit excl. impacts of Satsuma, FX and extraordinary gains/losses			
FY3/24	FY3/25		
	Full-year Forecast	YoY Changes	
264.5	298.3	+33.8	12.8%
55.0	56.4	+1.4	2.6%
83.0	86.4	+3.4	4.1%
68.7	72.3	+3.6	5.2%

# FY3/25 Financial Forecast: Quarterly OP (excl. Satsuma)



Quarterly operating profit forecast for FY3/25 excluding Satsuma's impacts.

# FY3/25 Forecast Earnings Structure



## Earnings Structure of FY3/25 forecast (¥M)

	FY3/24	FY3/25 (E)	Increase
Revenue	26,450	29,835	3,385
Gross Profit	14,282	16,328	2,046
<b>GP Ratio</b>	<b>54.0%</b>	<b>54.7%</b>	
SGA Expenses	10,120	13,977	3,857
Personnel	3,259	3,892	633
Commission	1,452	2,027	575
R&D	1,741	3,121	1,380
Breeding & Maintenance	1,333	1,835	502
Other	2,335	3,102	767
<b>SGA/Revenue Ratio</b>	<b>38.3%</b>	<b>46.8%</b>	
Operating Profit	4,162	2,350	-1,812
<b>OP Ratio</b>	<b>15.7%</b>	<b>7.9%</b>	
Share of profit of entities accounted for using equity method	2,751	2,981	
Of which, PPD-SNBL	2,632	2,772	140
FX Gains	60	0	-60
Ordinary Profit	7,015	5,345	-1,670
<b>Ordinary Profit Ratio</b>	<b>26.5%</b>	<b>17.9%</b>	

GP ratio will continue to improve, up by 0.7%, thanks to strong growth of contracts received and revenue in Nonclinical business, SNBL's main source of earnings.

Decrease of operating profit foreseen mainly due to the costs related to Satsuma Pharmaceutical's intranasal migraine drug STS101 for FDA approval (¥3.29B, up by ¥1.95B YoY).

Total personnel expenses, which is a sum of personnel expenses in SGA items and labor cost in cost of sales, expected to increase by 15.8%, (up by ¥1.66B YoY)

# Historical Financial Results by Segment



## Revenue & Profit/Loss by Segment

		(¥M)						
		FY 3/21	FY 3/22	FY 3/23	FY 3/24	Increase	FY 3/25(E)	Increase
<b>CRO Business</b>	Revenue	14,508	17,047	24,000	25,909	8.0%	29,247	12.9%
	OP	3,393	5,035	6,336	6,998	10.4%	7,906	13.0%
	OP Ratio	23.4%	29.5%	26.4%	27.0%		27.0%	
	Share of profit of entities accounted for using equity method	848	1,438	2,489	2,751	10.5%	2,981	8.4%
	of which, PPD-SNBL	864	1,258	1,967	2,631	33.8%	2,772	5.3%
	<b>Business Profit*</b>	<b>4,241</b>	<b>6,473</b>	<b>8,825</b>	<b>9,749</b>	<b>10.5%</b>	<b>10,887</b>	<b>11.7%</b>
<b>Translational Research Business</b>	Revenue	12	12	16	13		10	
	OP	-708	-746	-879	-2,465		-4,800	
	of which, Satsuma Pharmaceucirals				-1,344		-3,297	
<b>Medipolis Business</b>	Revenue	552	563	683	569		432	
	OP	-54	-17	-203	-254		-462	
<b>Other</b>	Revenue	503	968	1,437	1,407		2,062	
	OP	-35	41	110	88		20	
<b>Adjustments</b>	Revenue	-466	-844	-1,047	-1,448		-1,917	
	OP	-65	-116	-118	-205		-313	
<b>Total</b>	Revenue	15,110	17,748	25,090	26,450	5.4%	29,835	12.8%
	OP	2,529	4,195	5,245	4,162	-20.6%	2,350	-43.5%
	OP Ratio	16.7%	23.6%	20.9%	15.7%		7.9%	

Record-high revenue and profit expected in FY3/25

Increase of losses related to Satsuma Pharmaceuticals (-¥1.95B) is a main reason of decline in overall profit

\*Business Profit is a sum of operating profit and the share of profit of entities accounted for using equity method.



## ■ Foreign exchange gains/losses in non-operating items

### FY 3/24 results: FX gains ¥60M

FX assumption at the beginning of the fiscal year: 133.54yen/USD

FX assumption at the end of the fiscal year: 151.33 yen/USD

### FY 3/25 forecast: ±¥0

¥1 weaker against USD: -¥13M

## ■ FY 3/25 FX assumption: 145.00 yen/USD

## ■ Estimated PL impacts of ¥1 weaker against USD

Revenue: +¥52M

Operating profit: +¥13M

# Business Topics:

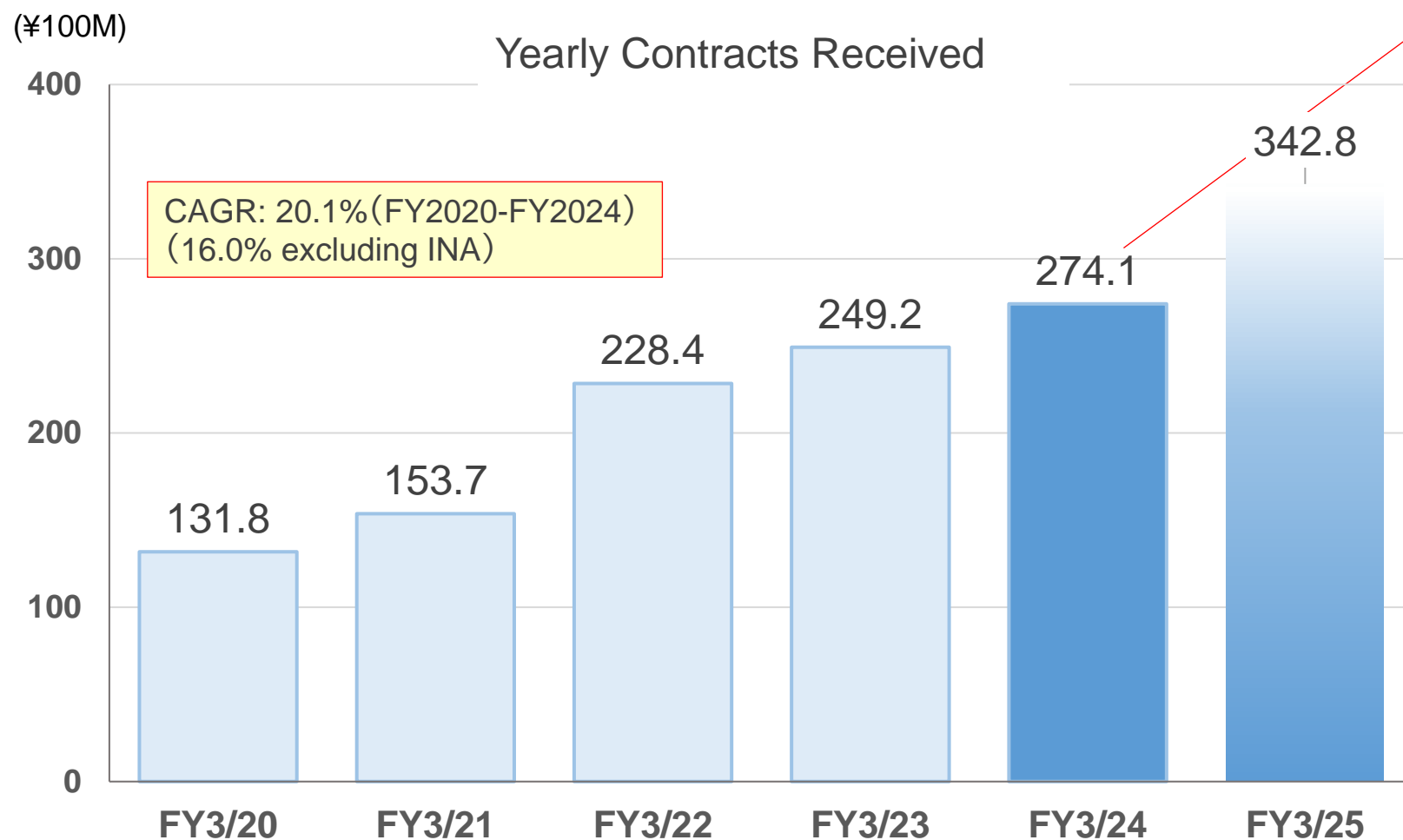
## I. CRO (Nonclinical)

---



Hideshi Tsusaki, DVM, PhD  
Executive Managing Director,  
President of Nonclinical Company and Global BD

# Contracts Received in FY3/24 (in JPY)



**Full-year YoY +¥2.49B**

**SNBL +¥1.76B**  
**Domestic: +¥3.57B**  
**Overseas: -¥1.81B**

**INA +¥0.73B**  
**Domestic: +¥0.45B**  
**Overseas: +¥0.28B**

FX rate (average for the period)  
¥145.31/USD

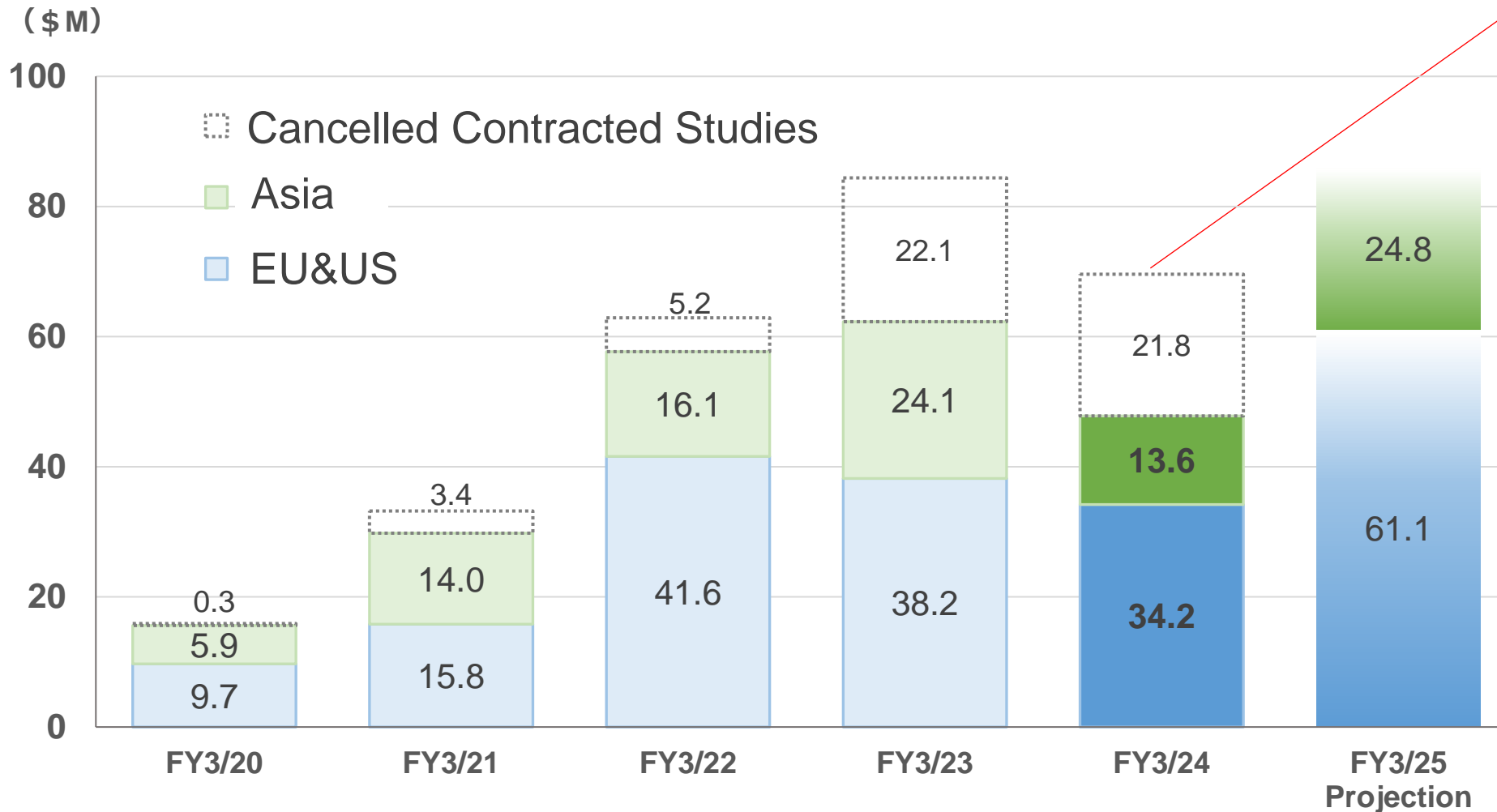
- Includes Ina Research from Q2 FY3/23
- Overseas contracts are converted to yen using the exchange rate at the end of each period

	FY3/20	FY3/21	FY3/22	FY3/23	FY3/24	FY3/25 Projection
Order Backlog at FY end	¥11.47B	¥13.66B	¥20.97B	¥29.25B	¥33.21B	
Overseas Ratio (%)	12.9%	20.6%	28.6%	34.4%	25.7%	

**Full-year YoY +¥3.96B**

**SNBL: +¥4.36B**  
**INA: -¥0.40B**

# Overseas Contracts Received in FY3/24 (in USD)



**Full-year YoY -US\$14.5M**

SNBL -US\$16.4M  
 EU&US: -US\$3.8M  
 Asia: -US\$12.6M

INA +US\$2.0M  
 EU&US: -US\$0.2M  
 Asia: +US\$2.2M

- Includes Ina Research from Q2 FY3/23
- Cancelled contracted studies are recorded as a negative figure at the time of cancellation

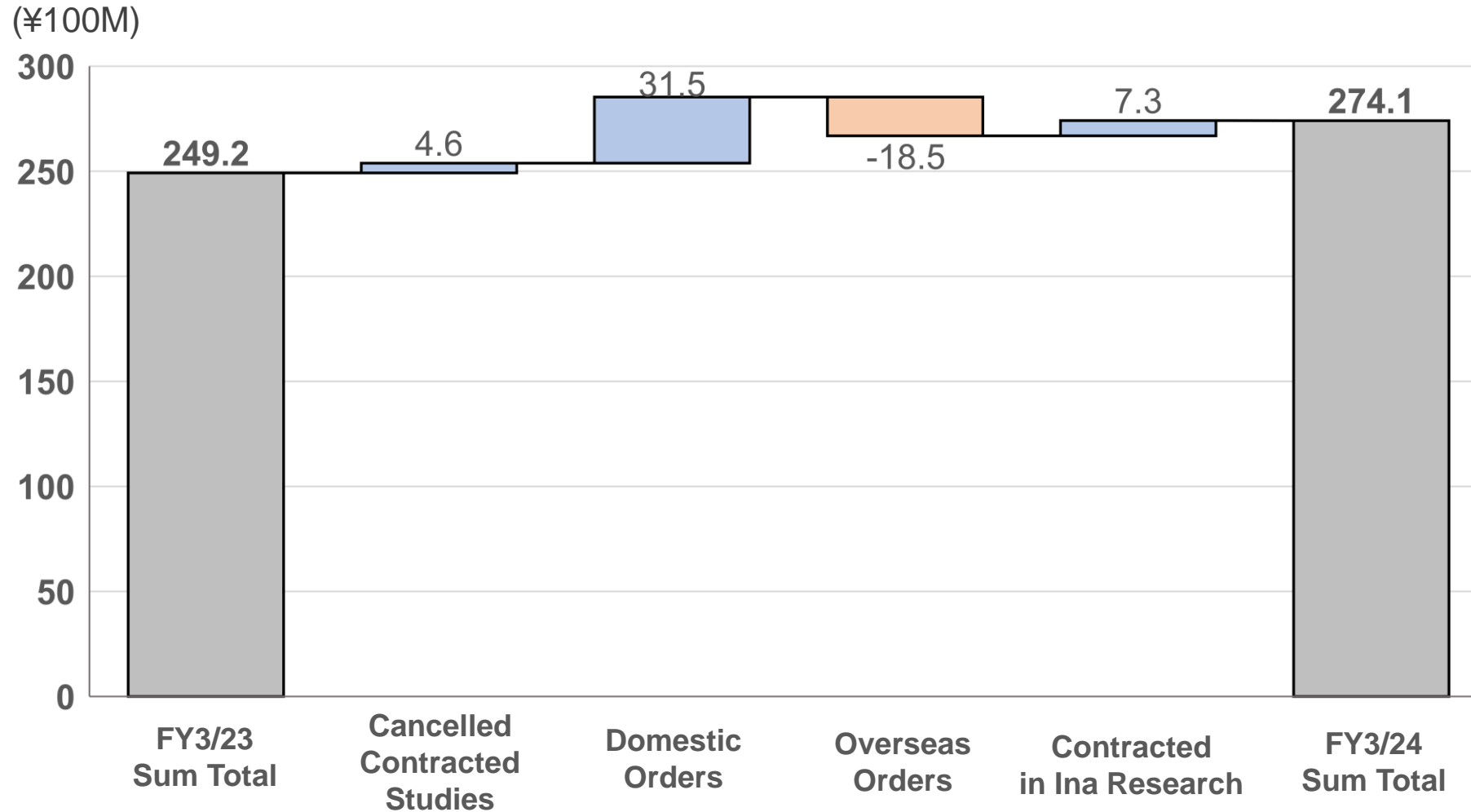
Order Backlog at FY end

<b>\$18.9M</b>	<b>\$36.0M</b>	<b>\$65.6M</b>	<b>\$101.6M</b>	<b>\$90.5M</b>
----------------	----------------	----------------	-----------------	----------------

**Full-year YoY -US\$11.1M**

SNBL : -US\$4.1M  
 INA : -US\$7.0M

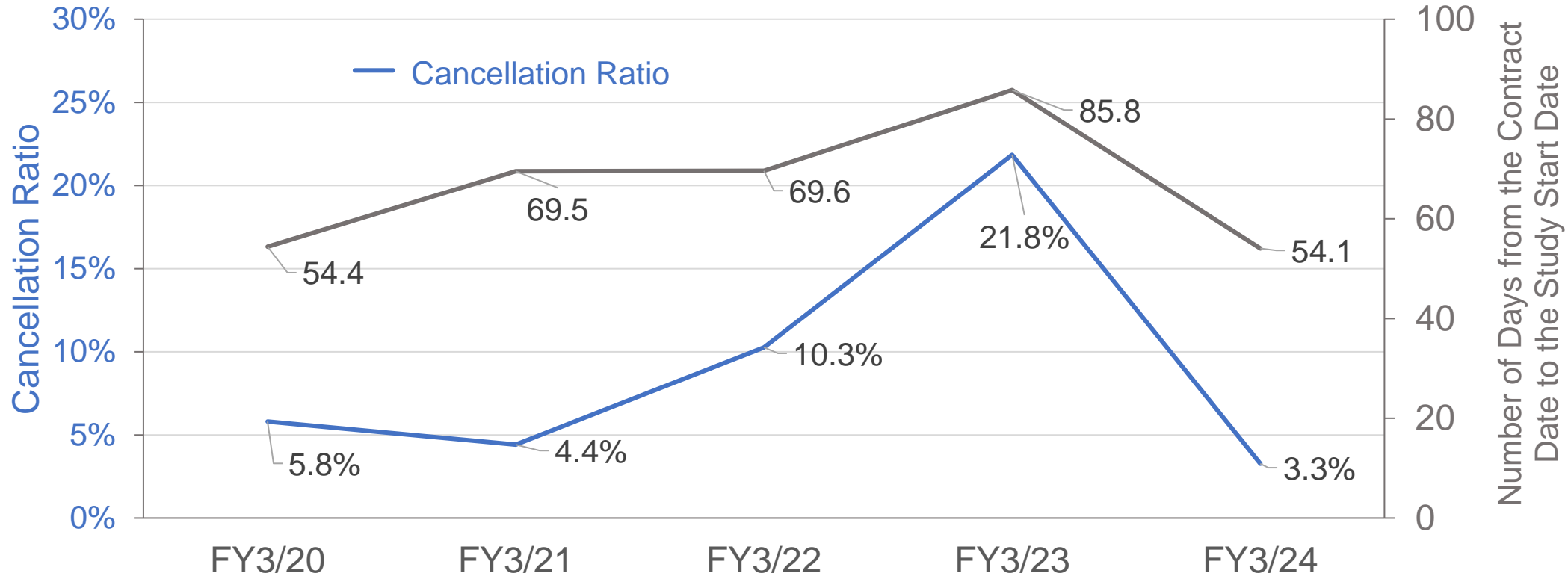
# Analysis of Contracts Received in FY3/24 (YoY)



- Includes Ina Research from Q2 FY3/23
- Cancelled contracted studies are recorded as a negative figure at the time of cancellation

Cancelled Contracted Studies: ¥4.17B (FY3/23) -> ¥3.71B (FY3/24)

# Cancellation of Contracted Studies Before Study Start



(¥100M)

Order Backlog at FY end

Order Backlog at FY end	131.8	153.7	228.4	249.2	274.1
Cancelled Amount	7.7	6.8	23.4	54.4	9.0

Cancelled Amount

- Includes Ina Research from Q2 FY3/23
- Cancelled contracted studies are recorded as a negative figure at the time of contract year

# Topics in FY3/24 in Nonclinical Business (1)



## Establishment of NHP Colonies Exclusively for Customers

- Established a dedicated NHP colony in response to requests mainly from overseas customers for stable and timely introduction of NHPs for study use, which is leading to additional revenue from the colony maintenance cost and further NHP study contracts in the future.

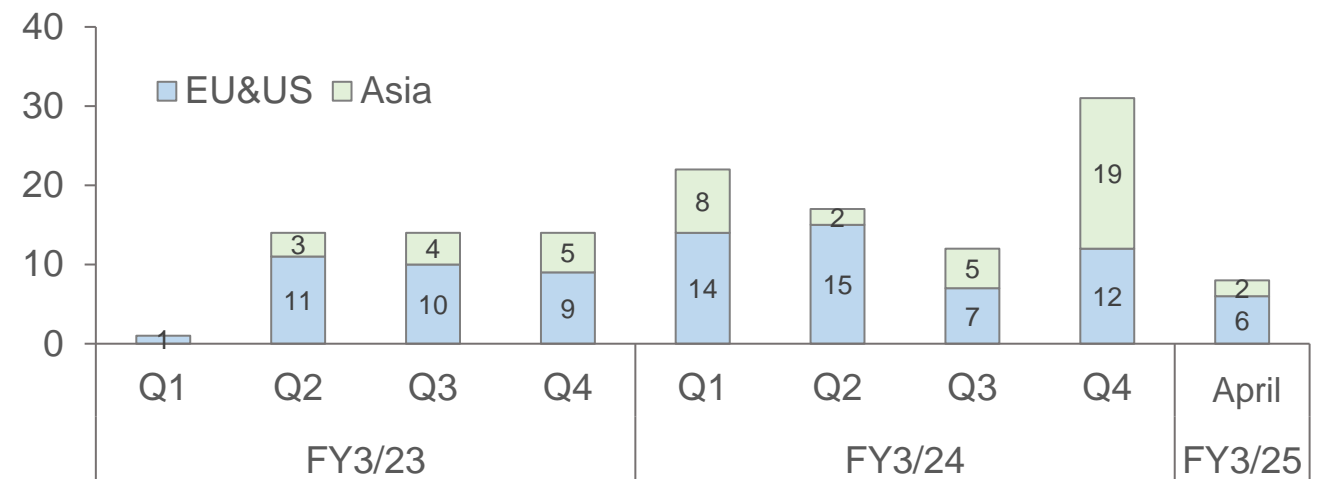
## Due Diligence toward Preferred Contracts with Major Overseas Pharmaceutical Companies

- Due diligence on our business for preferred contracts is in full swing with several major overseas pharmaceutical companies, with two of our target customers having ordered studies for the first time.

## Increase in Visits by Overseas Clients

- The number of visits by overseas clients, which had been decreasing due to the Covid-19, is increasing.

Number of Visits by Overseas Clients



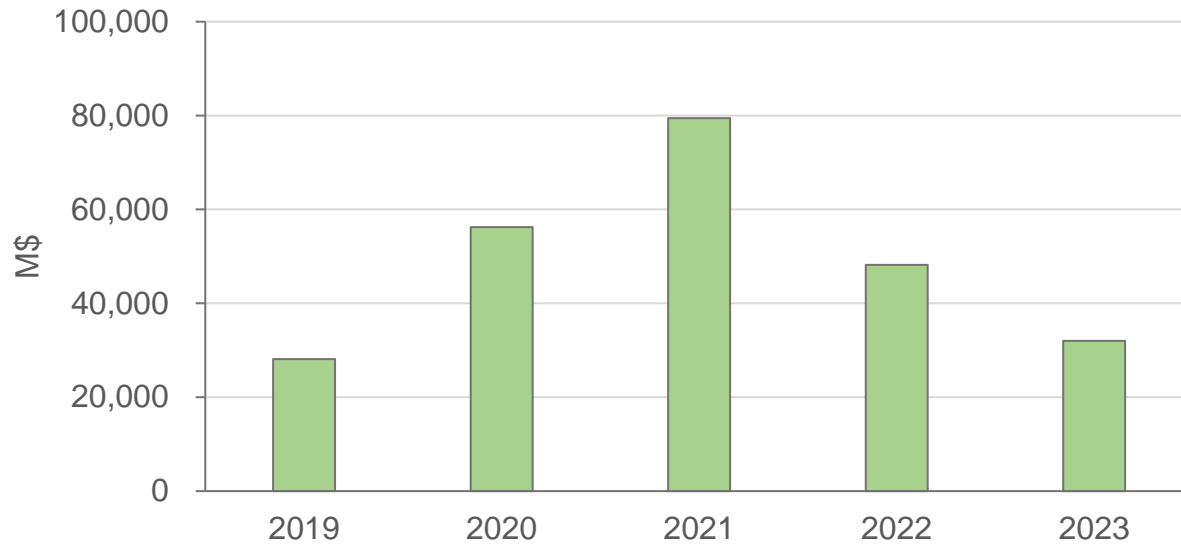
# Topics in FY3/24 in Nonclinical Business (2)



## Impact of Overseas Market Trends

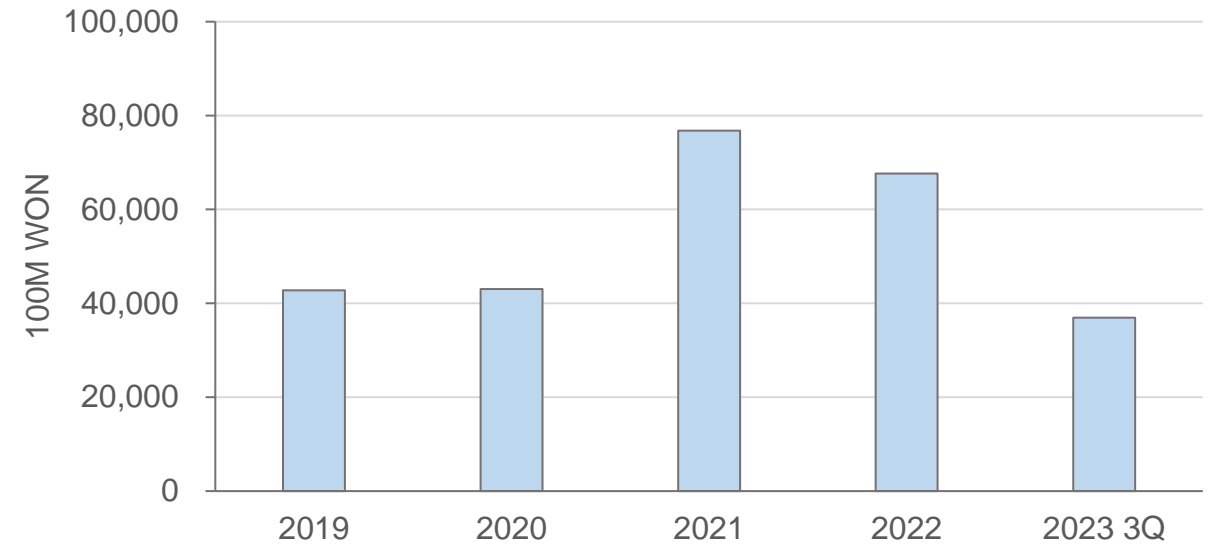
- Venture capital investments in Europe, the U.S., and South Korea continues to be weak. New orders, especially from South Korean bio ventures, declined from the previous fiscal year.

### Global Biotech Startup Funding Total



Reference : Modified Nikkei Biotech article (2023)

### New Venture Capital Investment in the Korean Biotech Market



Reference : BioINPro Vol 127. 2023

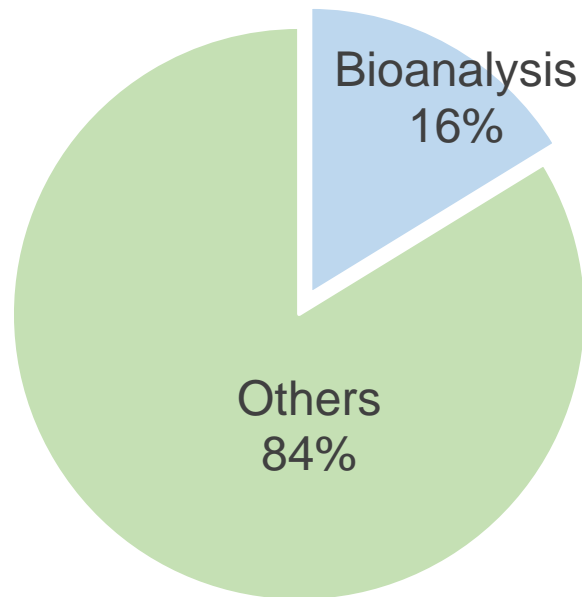


# Topics in FY3/24 in Nonclinical Business (3)

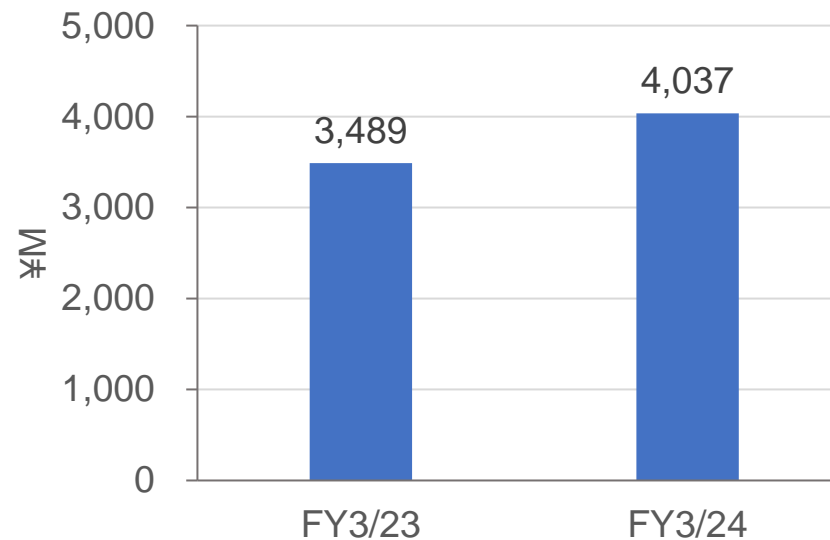
## Increase in bioanalysis contracts

- The number of bioanalysis contracts for blood drug concentration and blood biomarker analysis in non-clinical studies and clinical trials is increasing. Plans to expand the bioanalysis laboratory to meet further customer demand.

Ratio of Bioanalysis in FY3/24 Sales



Bioanalysis Sales Trends

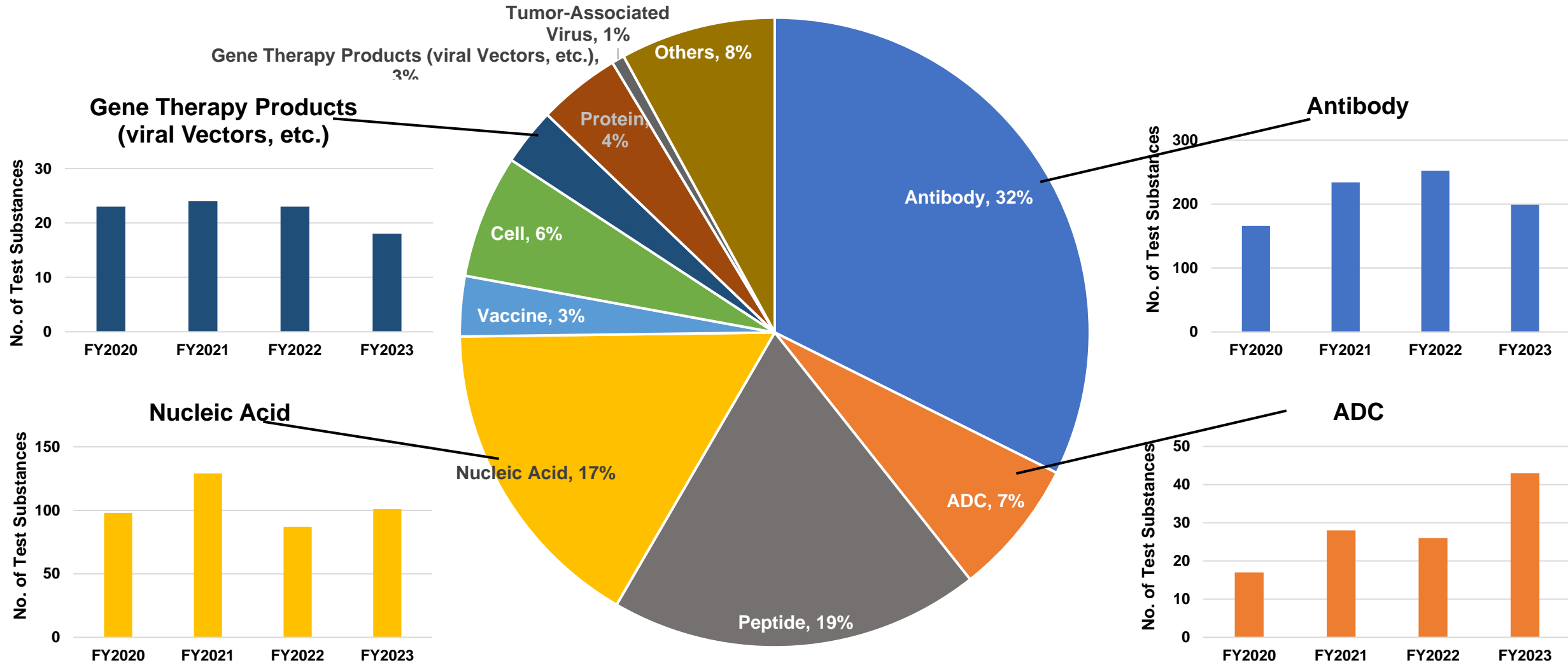


Conceptual Image of New Research Building



Construction to be Completed in May 2024

# Contracts by Drug Discovery Modality

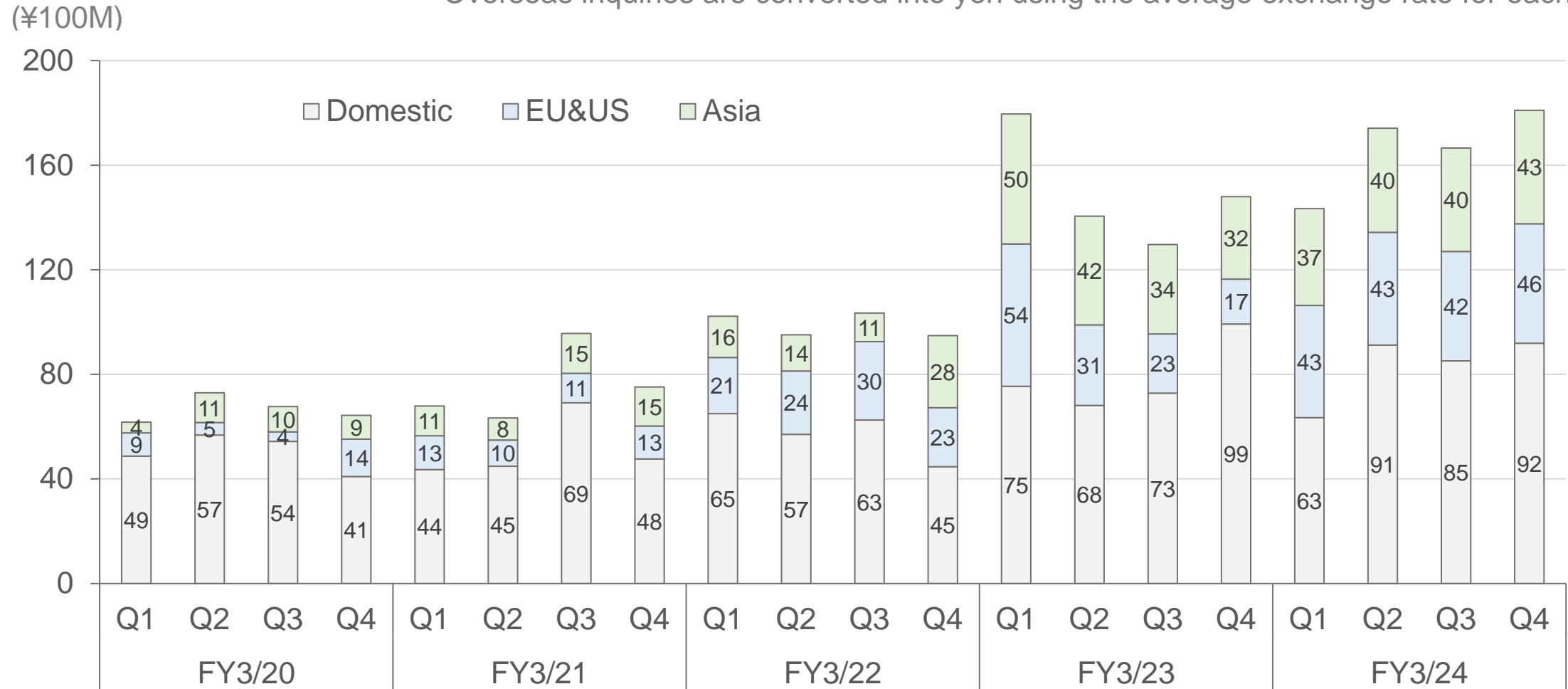


Contracts other than small molecule drugs for FY3/24 (No. of test substances): 615 Compounds

# Changes in Amounts of Quotations Submitted to Customers



\*Overseas inquiries are converted into yen using the average exchange rate for each period

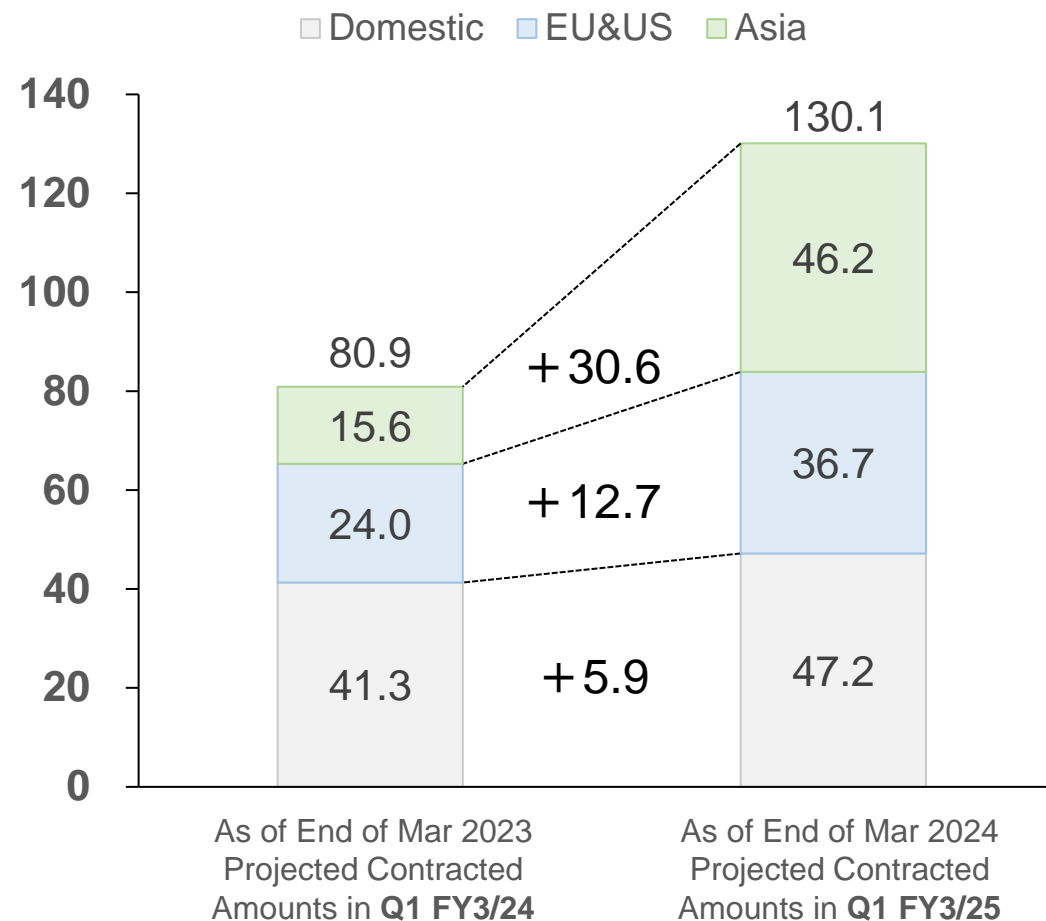
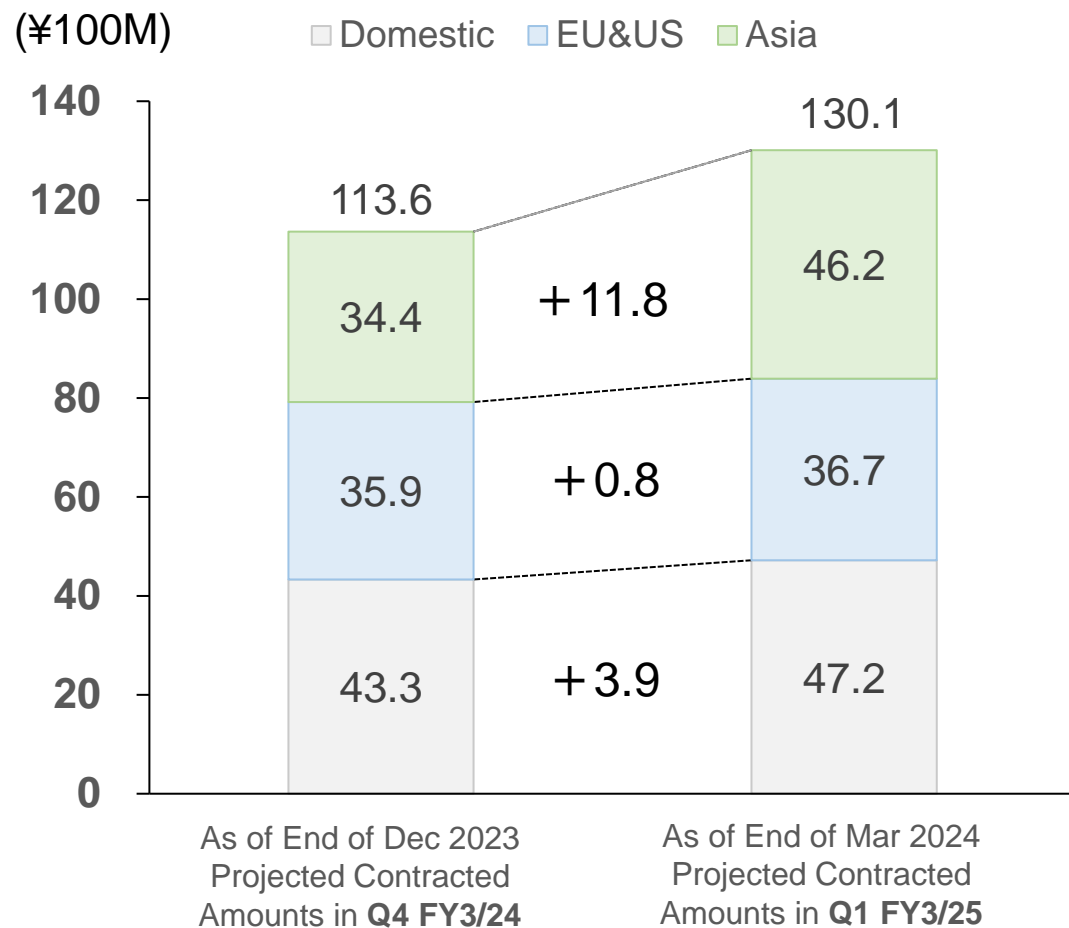


The total amount of quotations submitted to customers on a submission date basis is increasing year on year.

# Trend of Inquiries in FY3/24



\*Overseas inquiries are converted into yen using the average exchange rate for each period



Inquiries for Q1 FY3/25 contracts increased as of the end of March 2024

**Vision** Creation of a non-clinical R&D ecosystem to deliver new drugs to patients ASAP

## 1. Domestic Breeding and Supply System for Laboratory NHPs

New breeding and fostering facilities were newly opened in FY3/24 and will be expanded sequentially in FY3/25.

## 2. Expansion of Research Facilities

Construction of a new research building is scheduled for completion in May 2024.

## 3. Increase in Research Staff

96 new graduates were hired in April 2024. Mid-career hiring is also being actively implemented.

## 4. Launch of New Contracted Services

We are participating in the “Advanced Medical Technology Development Project for Industrialization of Regenerative Medicine and Gene Therapy (AMED)” and is working toward the social implementation of Microphysiological System (MPS).

## 5. Promotion of Digital Transformation

The DX project is being promoted from FY3/24. We are promoting automation and robotization of business processes to shorten lead time.

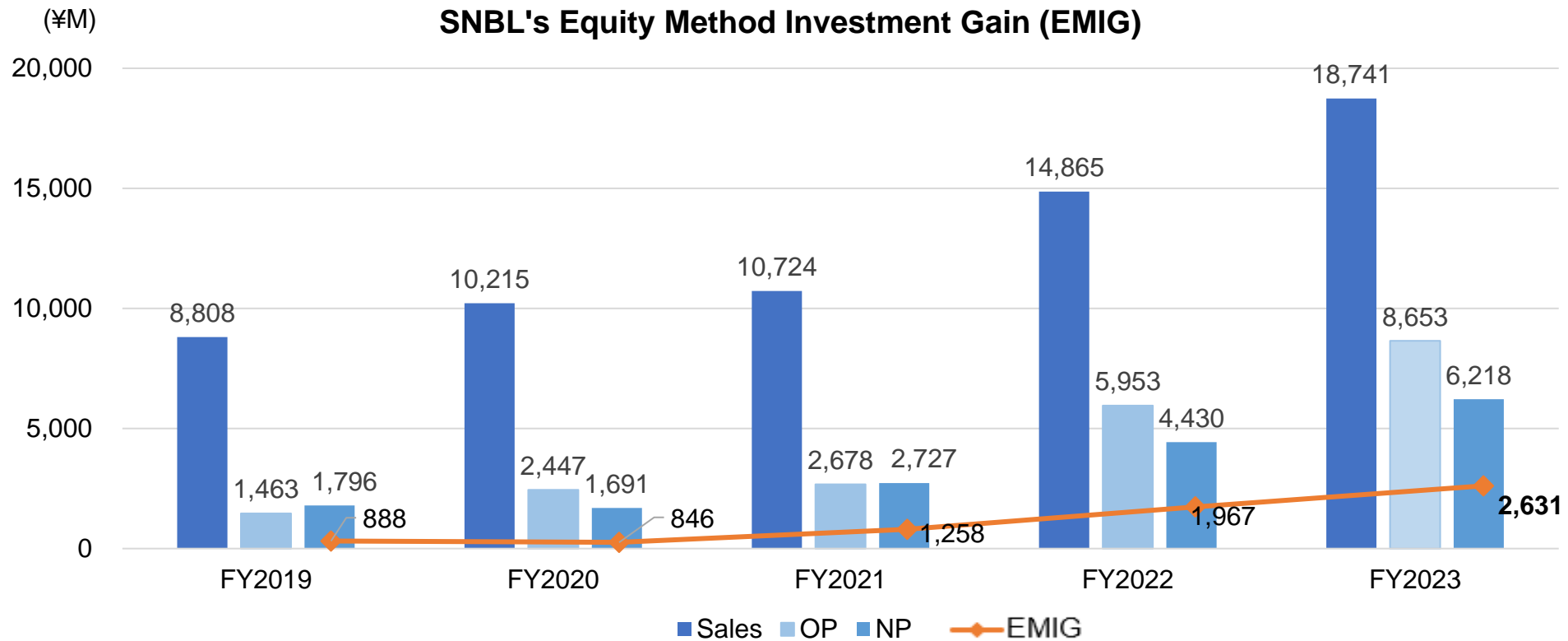
# Business Topics: II. CRO (Clinical)

---



Ichiro Nagata, MD, PhD, MMH, MBA  
Executive Vice President,

**PPD-SNBL Business Performance and SNBL's Equity Method Investment Gain (EMIG)**



**Revenue  
4 Year CAGR  
20.8%**

**Equity in Gain  
4 Year CAGR  
31.2%**

**#Employees**

717	732	760	835	945
-----	-----	-----	-----	-----

**Apr. 2024  
>1000**

# Business Topics:

## III. TR

---

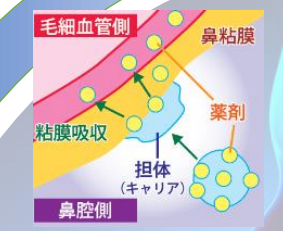
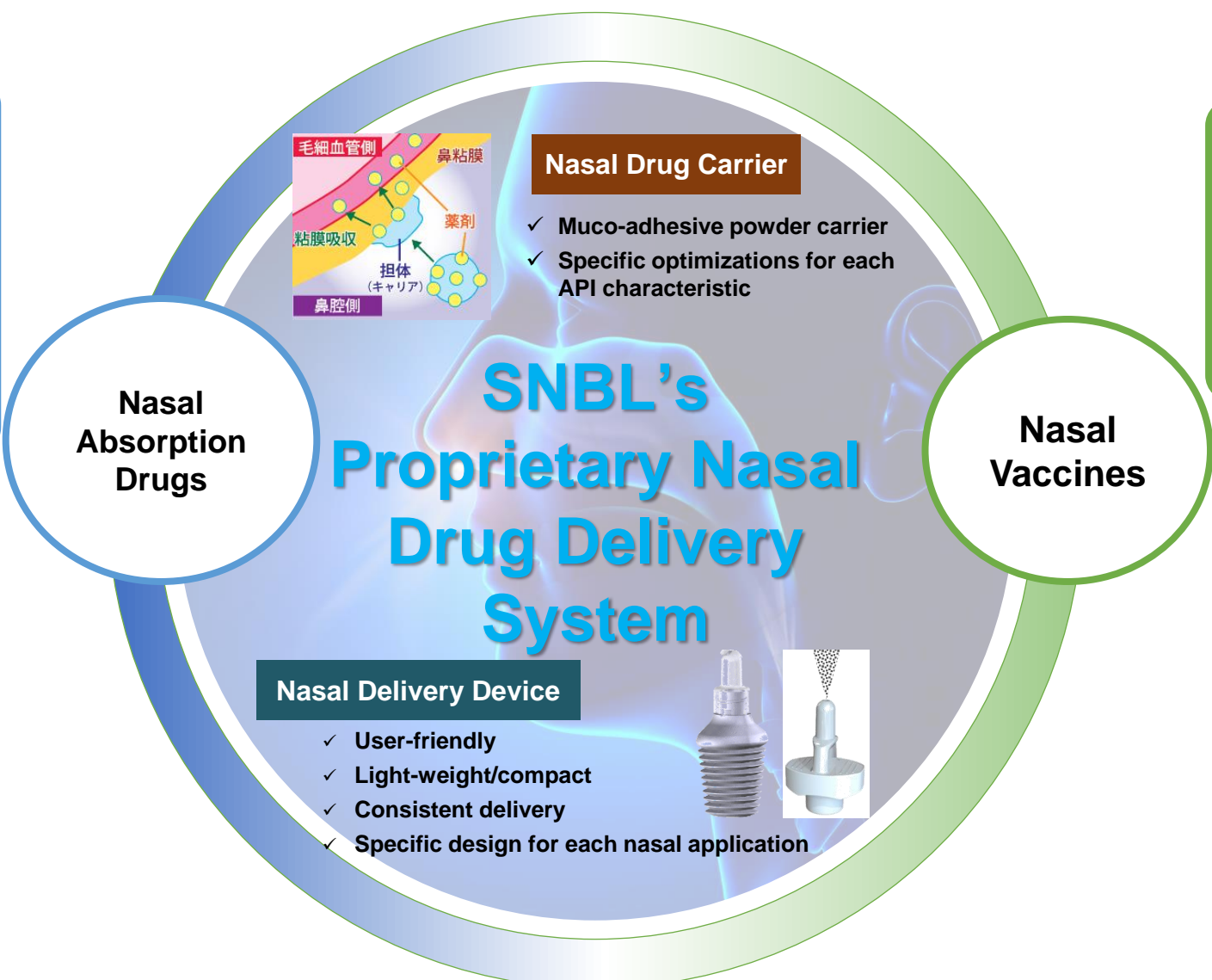


Ken Takanashi, MBA, CPA  
Senior Executive Vice President



**Satsuma**  
For relief acute migraine

**SNLD**  
For improvement the wearing-off in Parkinson's Disease



**R&D Center of Nasal Mucosal Vaccines**

Development of a powder formed nasal vaccine system that induce blocking immunity to the upper respiratory tract against multiple respiratory viruses

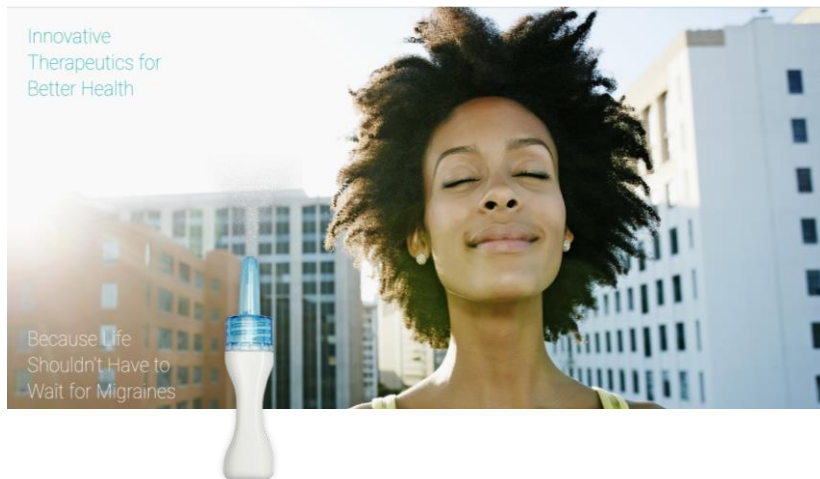
Research Grant

In the Scottsdale AHS Symposium on Nov 2023, Satsuma met 9 key opinion leaders and reacknowledged their strong expectations for STS101 in acute migraine treatments

**STS101 - the first and only DHE (dihydroergotamine) product with the potential for broad use in the acute treatment of migraine**



Specialty Pharma  
for Nasal Migraine Drug



## PROVEN

- ✓ DHE is regarded as a powerful anti-migraine agent with over 75 years of use by physicians
- ✓ DHE works through a unique multimodal mechanism of action unlike other treatments

## WELL TOLERABILITY & SAFE

- ✓ Lowest rates of adverse events for any non-oral acute migraine treatment
- ✓ Most common AEs in clinical trials were nasal discomfort (8.3%) and dysgeusia (3.7%)
- ✓ Reported AEs were mostly mild and transient

## TRANSFORMATIVE

- ✓ Easy-to use and easy-to-carry, proprietary DHE nasal powder formulation and device
- ✓ Advanced SMART platform provides rapid and sustained drug absorption
- ✓ Delivers the trusted and proven power of injectable DHE in a nasal powder

Jan 17, 2024 (US)

## **FDA Issued Complete Response Letter (CRL) for STS101**

- **The CRL did not indicate any concerns about the clinical data package in the NDA, and the FDA did not request any additional clinical trials to support the approval of STS101.**
- **The principal reasons described in the CRL relate to chemistry, manufacturing, and controls (CMC) and pre-clinical study considerations.**

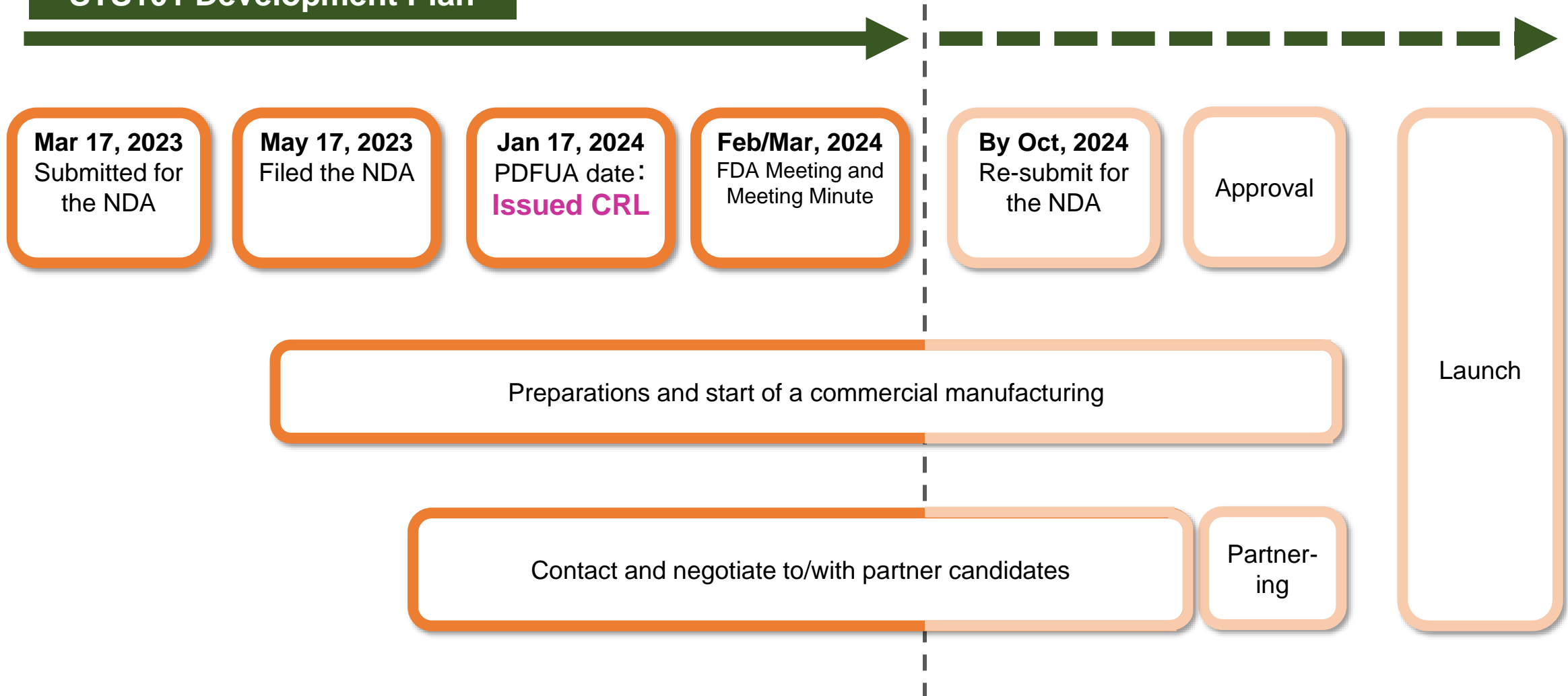
Feb 29, 2024 for FDA meeting and Mar 20, 2024 for FDA meeting minute (US)

- **The principal requirement for NDA resubmission has been limited to insufficient information on the registration batch related to CMC.**
- **A principal correction for the information is to add information including stability data on new formulation batches prepared in this Feb. to that on the registration batch.**

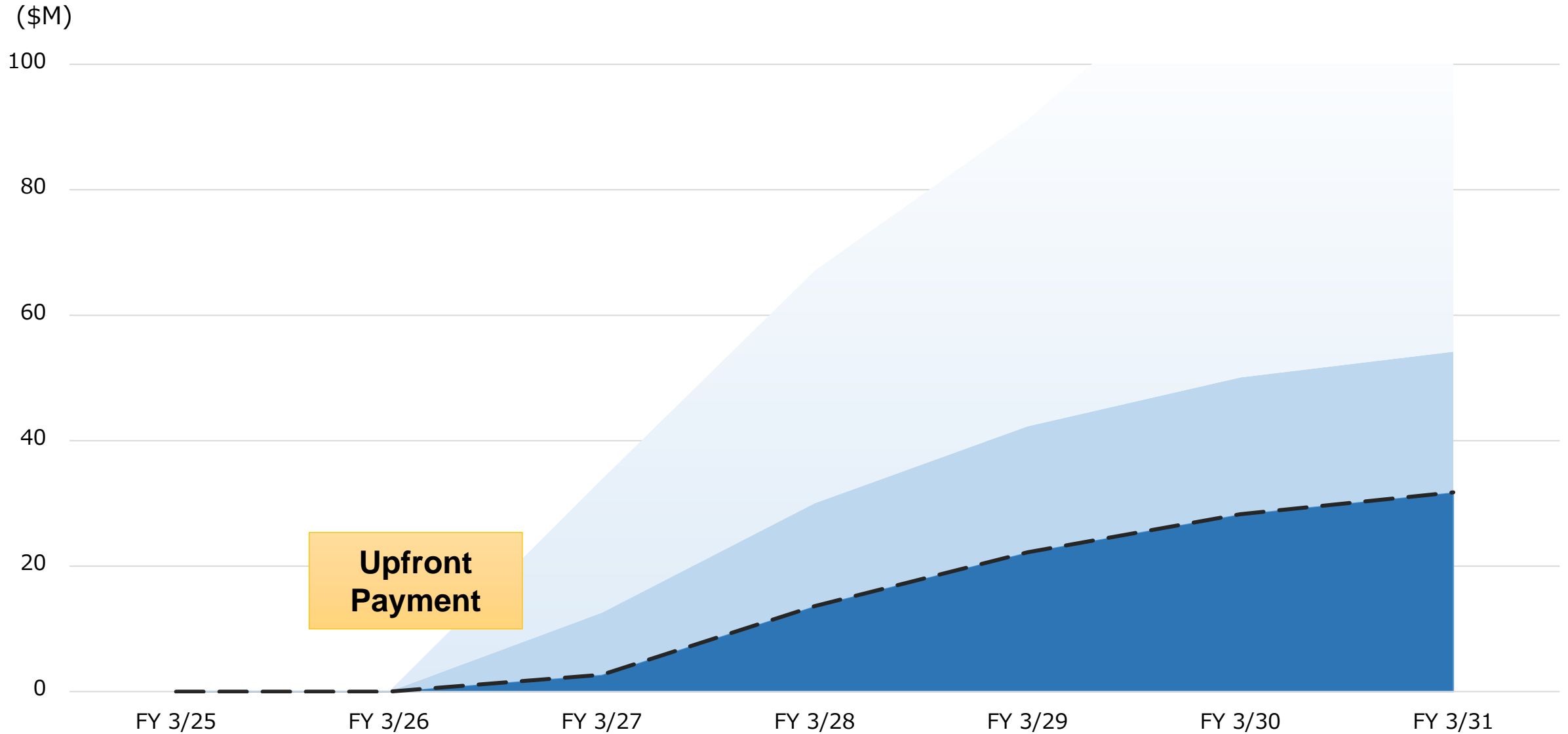
**After collecting formulation data required,  
Satsuma will resubmit for the NDA of STS101 by this Oct.**

# STS101 Development Plan

## STS101 Development Plan



# Conceivable Revenue Model for STS101



# Development of Parkinson's Disease Drug by SNLD



## Major Motor Symptoms of Parkinson's Disease



Shaking in a limb and hand



Stumbling

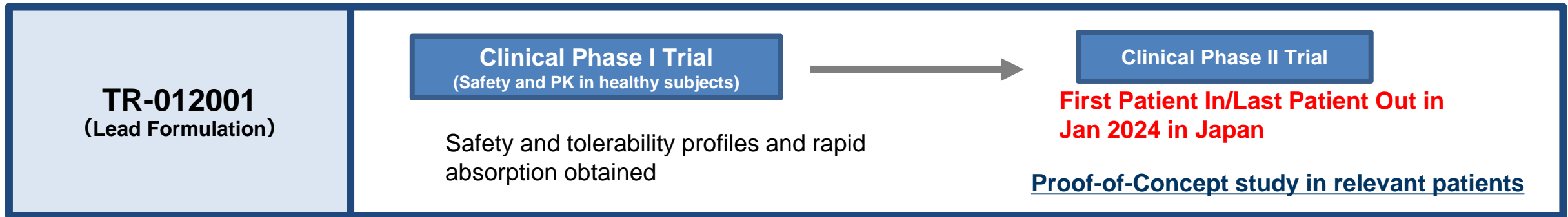


Lumbering and slow movement



Stiff muscles and/or joints

SNLD, Ltd., a 100% subsidiary of SNBL, is developing nasal delivery drugs as on-demand therapy to treat OFF episodes in Parkinson's Disease (PD), which are self-administrable and expected to have rapid onset of motor improvement



## Japan Agency of Medical Research and Development (AMED)

### Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA)

#### Mission

Achievement of Japanese-made safe and effective vaccines

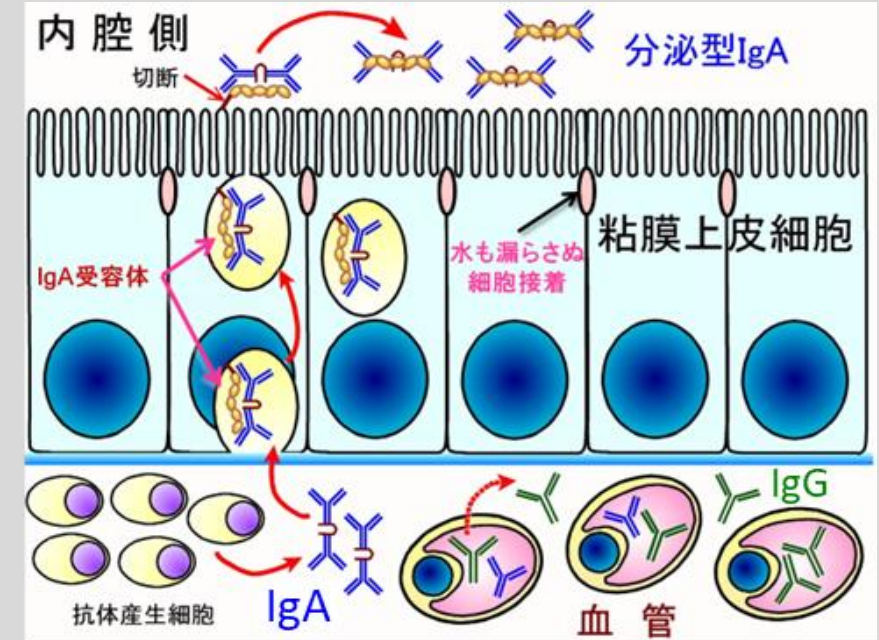
#### Vision

- Support a research and development system that can respond flexibly in preparation for the next “emergency.”
- Bring together the wisdom of industry, academia, and government to strengthen our world-class vaccine research and development infrastructure.

### FY2023 Program on R&D of new generation vaccine including new modality application

5 of adoption in 36 of application

Theme “Development of a TR’s nasal vaccine powder delivery system which generates IgA” has been adopted. Gain ¥100million as an initial research grant to assess a non-clinical POC of the system.



Source: SNBL, Ltd.

**Aim at clinical uses of powder type nasal vaccines which are intended to prevent an infection themselves (Blocking immunity).**

# Business Topics: IV. Medipolis

---



Ichiro Nagata, MD, PhD, MMH, MBA  
Executive Vice President,



## ■ Hospitality Business Division

- Contribution to the wellbeing of human beings through the hospitality business
- Cultivating “Omotenshi” mindset through the hospitality business, and applying and strengthening that mindset to CRO division

Image: Healing Resort Hotel “Amafuru”

## ■ Seedling Production of Glass Eels

- Conducting research on the artificial seedling production of glass eels, in order to protect the natural resources of Japanese eels, which are becoming increasingly depleted, and to contribute to the local community (Kagoshima Prefecture is the number one supplier of Japanese eels in Japan).
- FY2024/3 focused on expansion of the ability for the reproduction

Image: Artificial glass eels

## ■ Power Generation Business

- Since February 2015, a binary-type geothermal power plant with a rated capacity of 1,580kW has been in operation.
- FY 3/2024, from Q4, generator inspections and repairs were carried out, resulting in a decrease in electricity sales volume and facility operation rate due to the associated shutdown.
- FY 3/2025, from Q4, a hot spring power plant utilizing the hot spring source used for hotel bathing is scheduled to start FIT power sales.

【Results of Past 5- year Sales Electricity (kWh) and Utilization Rate 】

	FY3/20	FY3/21	FY3/22	FY3/23 * 2	FY3/24
Sales Electricity (kWh)	10,334,299	10,328,981	10,751,257	9,579,533	6,765,837
Utilization Rate (%) * 1	74.7	74.6	77.7	69.2	48.9

\* 1 An indicator that shows what percentage of the actual annual transmission volume of the power generation facility accounts for, compared to the transmission volume, if it operated continuously at 100% output. The higher this number, the more effectively the power generation facility is being utilized. Additionally, it is generally said that solar power is 13%, wind power is 20%, and geothermal power is 56% (according to the “2021 Fiscal Year Supply Plan Summary” by the Wide-Area Operation Promotion Organization).

\* 2 For the fiscal year ending March 2023, due to the statutory inspection including turbine open inspections, the downtime was longer than usual, resulting in a decrease in electricity sales volume and facility utilization rate.

# 4. Q&A





## Financial Data

(In millions of yen)	FY 3/2019	FY 3/2020	FY 3/2021	FY 3/2022	FY 3/2023	FY 3/2024	FY 3/2025 Forecast
Revenue	15,658	14,561	15,110	17,748	25,090	26,450	29,835
YoY(%)	-5.7%	-7.0%	3.8%	17.5%	41.4%	5.4%	12.8%
Gross profit	6,177	7,615	7,554	9,687	13,046	14,282	16,308
Ratio of gross profit to revenue (%)	39.5%	52.3%	50.0%	54.6%	52.0%	54.0%	54.7%
Operating profit	829	2,228	2,529	4,195	5,245	4,162	2,350
YoY(%)	-	168.5%	13.5%	65.9%	25.0%	-20.6%	-43.5%
Share of profit of entities accounted for using equity method	361	888	846	1,439	2,489	2,751	2,981
Ordinary profit	1,613	3,121	3,645	7,078	9,194	7,015	5,345
Profit before income taxes	1,650	3,062	4,175	8,183	7,759	6,974	--
Income taxes	-308	414	497	1,016	1,708	1,456	--
Profit attributable to owners of parent	1,950	2,550	3,661	7,127	6,060	5,531	3,920
Profit per share (yen)	46.84	61.25	87.95	171.20	145.56	132.86	94.15
Overseas sales	4,015	2,317	2,100	3,091	6,575	8637	--
Overseas sales ratio	25.6%	15.9%	13.9%	17.4%	26.2%	0	--
Revenue from international sponsors	9,958	12,386	15,840	22,181	25,751	29,252	--
Net assets	28,477	16,381	15,838	19,723	26,359	34,160	--
Total assets	54,329	39,002	36,972	39,312	57,242	76,302	--
Interest-bearing debt	16,158	15,123	12,864	9,281	18,931	26,331	--
Equity ratio (%)	52.3%	41.8%	42.6%	49.8%	45.8%	44.7%	--
Capital expenditures	1,612	1,514	1,025	1,703	5,614	8,525	10,559
Depreciation	1,361	1,229	1,187	1,177	1,544	1,774	2,751
R&D expenses	339	400	392	425	683	1,741	3,121
Ratio of R&D expenses to revenue (%)	2.17%	2.75%	2.59%	2.39%	2.72%	6.58%	10.46%
Number of employees at the end of the fiscal year	935	985	986	994	1,208	1,341	1,465
ROE (%)	7.1%	11.4%	22.9%	40.4%	26.5%	18.3%	--
ROA (%)	2.9%	6.7%	9.6%	18.6%	19.0%	10.5%	--
ROIC (%)	--	11.7%	12.3%	18.4%	17.9%	10.3%	--
Ratio of operating profit to revenue (%)	5.3%	15.3%	16.7%	23.6%	20.9%	15.7%	7.9%
Ratio of ordinary profit to revenue (%)	10.3%	21.4%	24.1%	39.9%	36.6%	26.5%	17.9%
Cash dividends per share (yen)	3.0	5.0	20.0	40.0	50.0	50.0	50.0
Dividend payout ratio (%)	6.4%	8.2%	22.7%	23.4%	34.3%	37.6%	53.3%

1. Projected results are based on information available to the Company at the time of writing, as well as certain assumptions judged by the Company to be reasonable. Various risks and uncertain factors could cause actual results to differ materially from these projections. This material does not constitute a solicitation of application to acquire or an offer to sell any security in Japan or elsewhere. This material is presented to inform stakeholders of the views of SNBL's management but should not be relied on solely in making investment and other decisions. You should rely on your own independent examination of us before investing in any securities issued by our company. SNBL shall accept no responsibility or liability for damage or loss caused by any error, inaccuracy, misunderstanding or changes of target figures or any other use of this material.
2. Information about pharmaceutical products (including products currently in development) included in this material is not intended to constitute an advertisement nor medical advice.
3. The presentation slides are based on "Summary of Consolidated Financial Results for the Fiscal Year Ended March 31, 2024 (Japanese GAAP).“ Figures rounded to the nearest 100 million Japanese yen and percentage to one decimal place.
4. This English presentation was translated from the original Japanese version. In the event of any inconsistency between the statements in the two versions, the statements in the Japanese version shall prevail.

## <IR Inquiries>



Shin Nippon Biomedical Laboratories, Ltd.  
IR & Corporate Communications

Phone: +81 03-5565-6216  
E-mail: [ir@snbl.com](mailto:ir@snbl.com)  
Website: <https://www.snbl.co.jp>