

# The Fiscal Year Ending March 31, 2023 1H Financial Results Presentation

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November 2, 2022



SHIN NIPPON BIOMEDICAL LABORATORIES, LTD.

(TSE PRIME: 2395)



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# 1. 1H FY2022/3 Overview & Future Outlook

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Ryoichi Nagata, MD, PhD, FFPM

Representative Chairman and President, CEO and CHO

# Summary

## 1. FY2023/3 1H Results

- Revenue and all levels of profits posted record-highs for 1H.
- Driven by the industry-wide trend of accelerating R&D activities targeting new drug modalities, overseas orders related to nonclinical business dramatically increased by 107% yoy, accounting for 43% of the total orders received.
- Revenue and profits of the newly subsidized Japanese nonclinical CRO, Ina Research, for three months from July to September, also contributed to the 1H results.
- Bestowed payment of interim dividends for the first time since IPO.



## 2. FY2023/3 2H Forecasts & Future Direction

- Refurbish and expand existing facilities and substantially increase the number of lab personnel in the view that the CRO industry will continue to thrive.
- A licensee of SNBL's proprietary nasal drug delivery platform technology is expected to announce its Phase 3 clinical study's results by the end of 2022.
- Starting construction of the new HQ building and lab facilities by the end of 2022 to further accelerate our sustainable growth.

## 3. Initiatives to Enhance Corporate Values : SDGs/ESG

- Published the Company's first Integrated Report in October.
- Focus on employees' happiness: paid extra bonus to all employees as support measures against inflation.
- Improved ESG rating agencies' scores; selected as a constituent of the FTSE Blossom Japan Sector Relative Index.



## 2. Outline of 1H Consolidated Financial Results

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Shinji Nitanda  
Senior Managing Executive Officer

# FY2023/3 1H Consolidated Financial Results Highlights

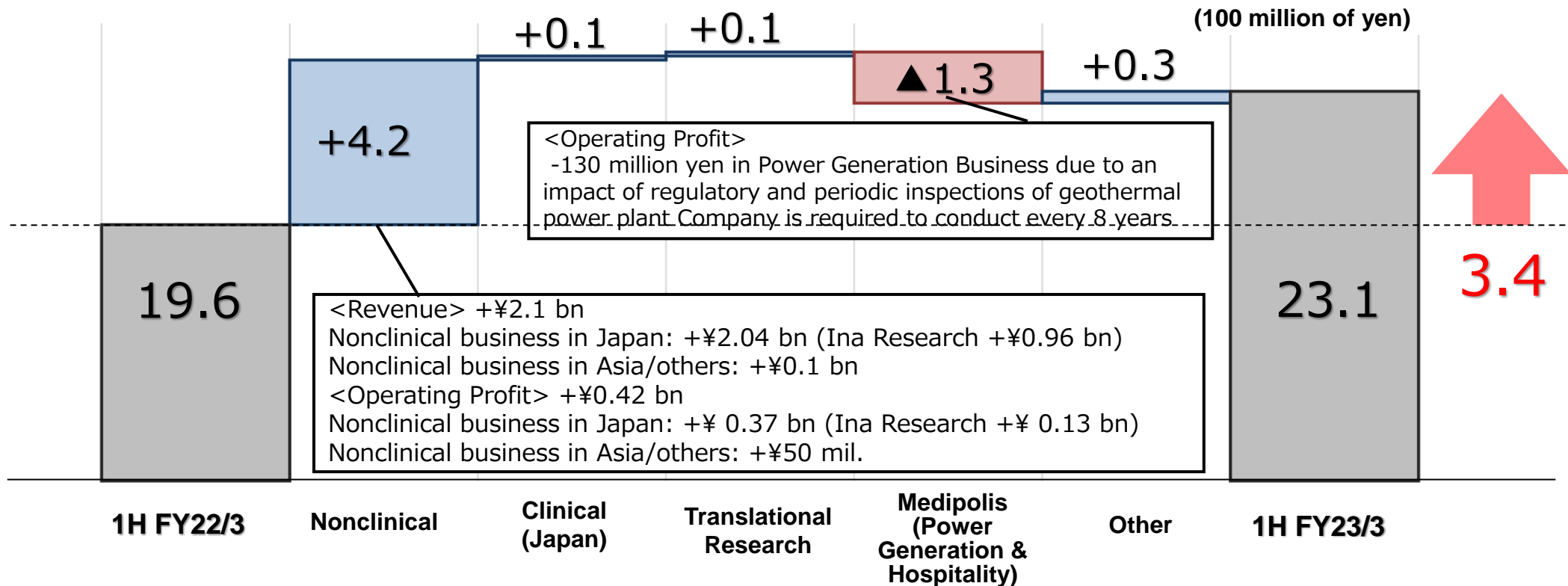
**Record-high revenue** was posted for the first half of fiscal year thanks to a contribution of 3 months (July to September) revenue of Ina Research Inc., and **all profits also broke the previous records** as they did the same period last year. Ordinary profit significantly exceeded the previous forecasts announced in July, backed by strong business performance of PPD-SNBL and FX gain of ¥0.89 bn newly occurred in 2Q. Revenue and operating profit fell below the forecasts as a part of nonclinical contracted researches originally projected in the first half have been reallocated to the second half of the fiscal year.

(100 million of yen)

	FY2022/3 1H Results	FY2023/3				
		Previous Forecasts (29/7/2022)	<b>1 H Results</b>	Changes against Previous Forecasts	Yoy	
Revenue	79.6	105.7	<b>103.4</b>	<b>-2.2</b>	<b>+23.8</b>	<b>30.0%</b>
Operating Profit	19.6	25.1	<b>23.1</b>	<b>-1.9</b>	<b>+3.4</b>	<b>17.5%</b>
Ordinary Profit	25.2	47.0	<b>59.2</b>	<b>+12.2</b>	<b>+33.9</b>	<b>134.4%</b>
Ordinary Profit (excl. FX impact)	23.7	30.0	<b>33.4</b>	<b>+3.3</b>	<b>+9.6</b>	<b>40.6%</b>
Profit Attributable to Owners of Parent	35.0	33.1	<b>44.1</b>	<b>+11.0</b>	<b>+9.1</b>	<b>26.1%</b>

# Yoy Comparison of 1H Consolidated Operating P/L

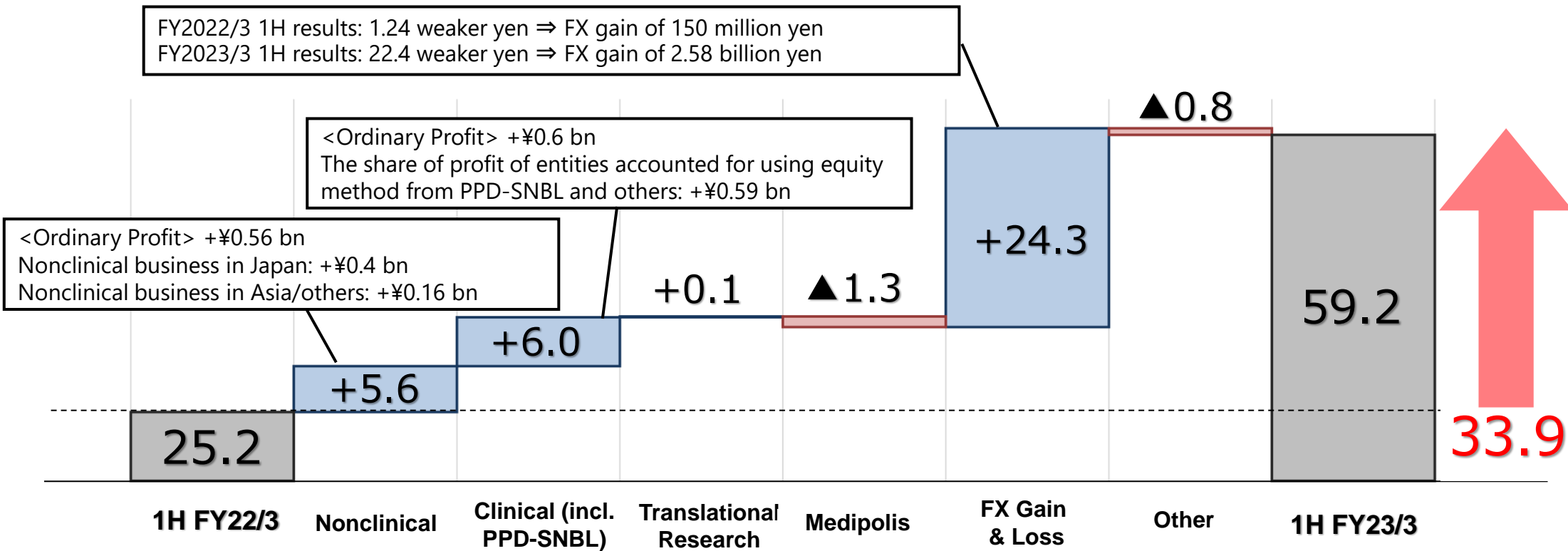
	CRO Business		Translational Research Business	Medipolis Business (Power Generation & Hospitality)	Other	Operating Profit Total
	Nonclinical	Clinical (Japan)				
1H FY2023/3	28.5	0.1	-3.2	-1.4	-0.9	23.1
1H FY2022/3	24.3	0.0	-3.3	-0.1	-1.3	19.6
Yoy changes	+4.2	+0.1	+0.1	-1.3	+0.3	+3.4



# Yoy Comparison of 1H Consolidated Ordinary P/L

	CRO Business		Translational Research Business	Medipolis Business (Power Generation & Hospitality)	Foreign Exchange Gain & Loss	Other	Ordinary Profit Total
	Nonclinical	Clinical (incl. PPD-SNBL)					
1H FY2023/3	29.7	10.3	-3.2	-1.4	25.8	-2.0	59.2
1H FY2022/3	24.1	4.3	-3.3	-0.1	1.5	-1.3	25.2
Yoy Changes	+5.6	+6.0	+0.1	-1.3	+24.3	-0.8	+33.9

(100 million of yen)





# FY2023/3 Full-year Forecasts Revisions

Revenue and all profits are upwardly revised in view of recent foreign exchange and currency trends.

(100 million of yen)

## <FY2023/3 forecast keypoints>

### 1. Revenue

Revenue expected to increase by ¥1.17 bn compared to the previous forecasts:  
 +¥0.89 bn in Nonclinical Business in Japan including +¥0.2 bn from Ina Research, and +¥0.28 bn from US/others.

### 2. Operating Profit

OP expected to increase by ¥50 mil: +¥0.34 bn in gross OP in Nonclinical Business in Japan, -¥0.15 bn in enhancement of lab animal breeding system, and -¥0.14 bn in increased corporate expenses including payment of extra bonus to employees as support measures against inflation.

### 3. FX gains and losses (non-operating profit/loss)

Concerning loans to subsidiaries, FX valuation increase of ¥0.89 bn compared to the previous forecasts was posted due to JPY/USD fluctuation (¥8.17 weaker yen):

- Previous FX assumption: JPY/USD136.64
- Actual FX rate (30/9/2022):JPY/USD144.81

\*FX assumption for revised forecasts: JPY/USD144.81

### <FX Sensitivity>

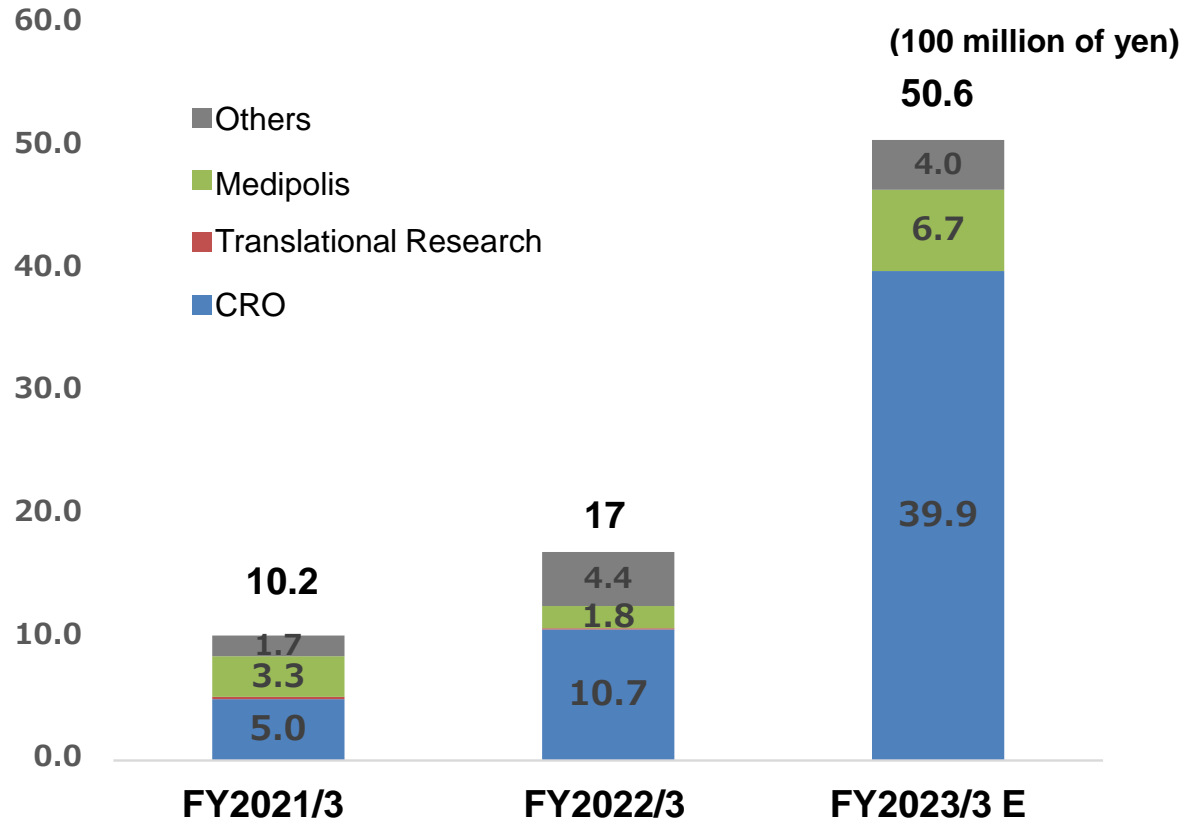
Estimated impacts of 1 weaker yen against USD in 2H FY2023/3 are as below:

- Revenue: +¥19 mil
- OP: +¥12 mil
- Non Operating P/L: +¥0.11 bn

	FY2023/3				
	Revised Forecasts	Changes against previous forecasts (29/7/2022)		Yoy Changes	
Revenue	<b>240.0</b>	<b>+11.7</b>	<b>5.1%</b>	<b>+62.5</b>	<b>35.2%</b>
Operating Profit	<b>52.6</b>	<b>+0.5</b>	<b>1.0%</b>	<b>+10.6</b>	<b>25.4%</b>
Ordinary Profit	<b>98.0</b>	<b>+19.1</b>	<b>24.2%</b>	<b>+27.2</b>	<b>38.5%</b>
Ordinary Profit (excl. FX impact)	<b>72.1</b>	<b>+10.1</b>	<b>16.3%</b>	<b>+15.0</b>	<b>26.4%</b>
Profit Attributable to Owners of Parent	<b>70.0</b>	<b>+14.1</b>	<b>25.2%</b>	<b>△1.2</b>	<b>-1.8%</b>

# CAPEX

**CRO(Nonclinical) Business and Medipolis (Power Generation) Business are areas of investment focus for FY2023/3. New construction of research facilities, with total construction costs of approx. 5.4 bn yen will increase SNBL's contracts research capacity by 50%.**



Perspective drawing of Kagoshima New HQ and Research Buildings

### <Overview>

**Name:** Kagoshima new HQ and research buildings  
**Address:** 2438 Miyanoura-cho, Kagoshima-city, Kagoshima Pref.

**TFA:** 13,018m<sup>2</sup>

**Structures:** two 8-storied reinforced concrete buildings

**Purpose:** office and research lab

**Start of Construction:** by the end of 2022

**Completion of Construction:** June, 2024 (planned)

	FY2021/3	FY2022/3	FY2023/3	
			Forecasts	Yoy
<b>CAPEX</b>	10.2	17.0	50.6	+33.6
<b>Depreciation</b>	11.8	11.7	14.5	+2.8

## 3 . Business Topics: CRO (Nonclinical) Business

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Hideshi Tsusaki, DVM, PhD  
Senior Executive Director,  
President of Preclinical Business and Global BD

# CRO Business: Acquisition of Ina Research Inc

**Operated since 1974,  
and well known in the industry**

**Full services provider as  
a non-clinical CRO**

**Contract with many Asian,  
especially Korean clients**

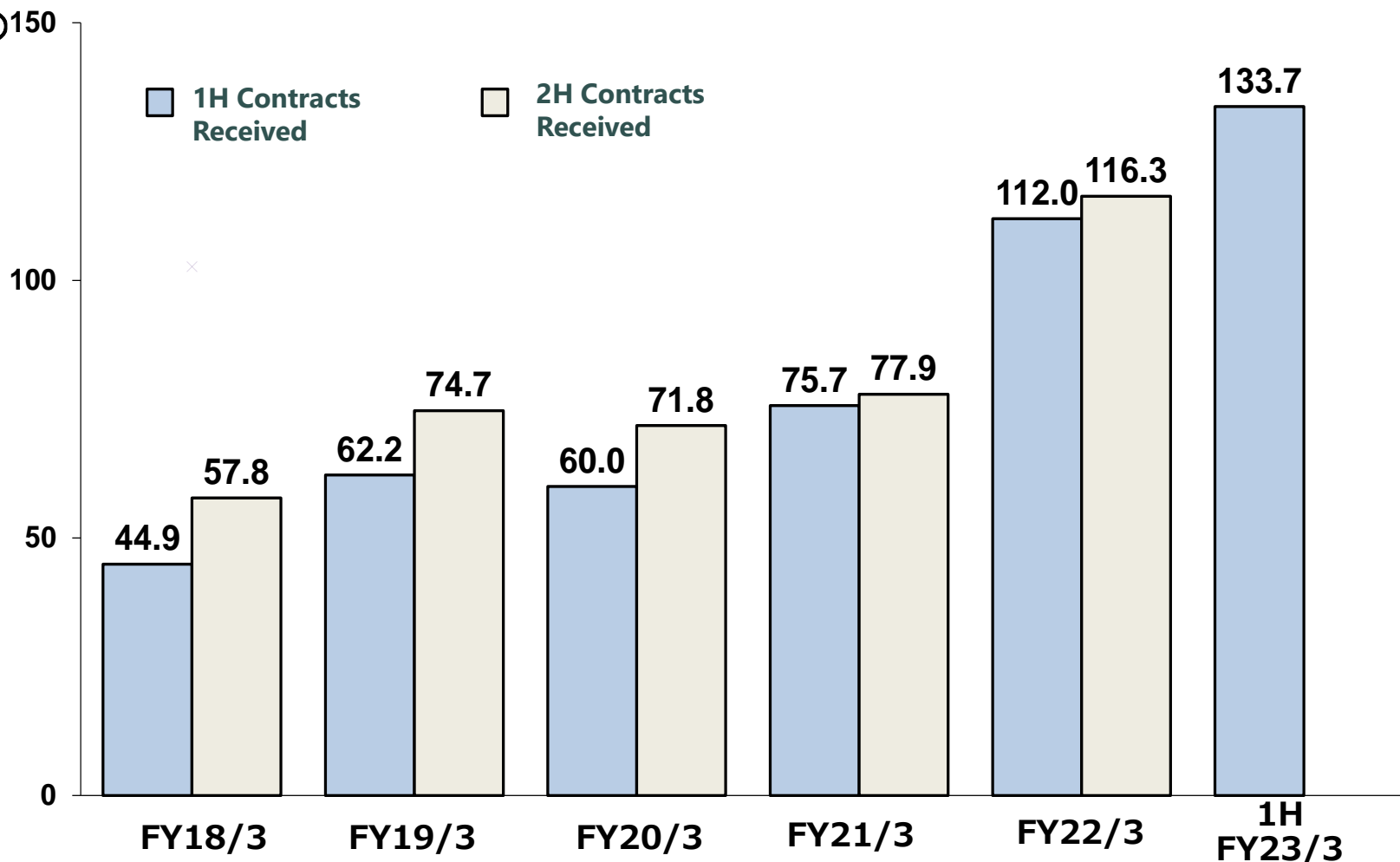


## Our aims for the acquisition

- **Expand our client base**
- **Provide more flexible services based on the increased capacity**
- **Increase the study types and deepen the quality of services by collaborating each site**

# CRO Business: Contracts Received in Nonclinical Business in 1H FY2023/3

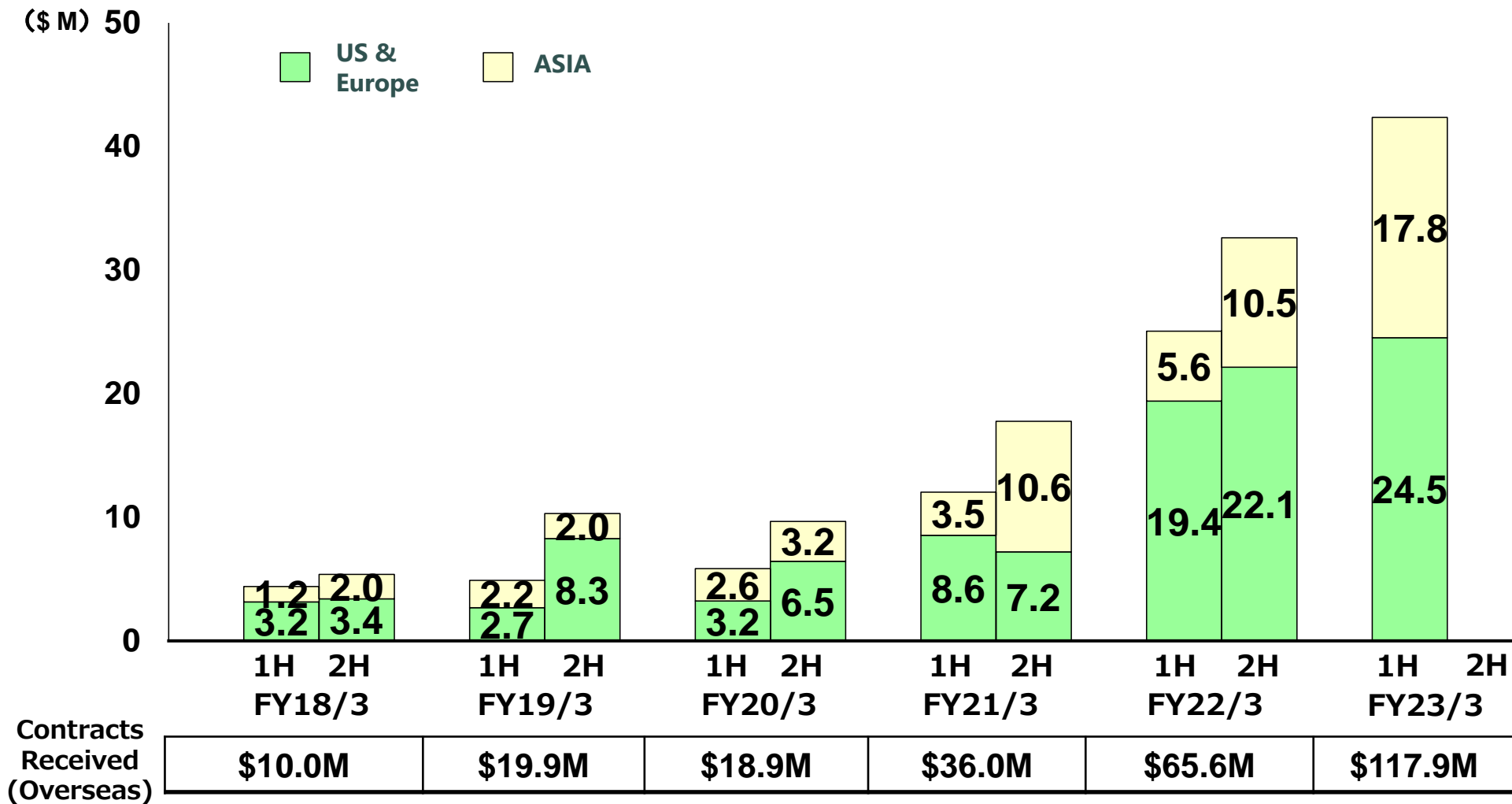
(100 million of yen)150



Backlog	74.9	108.2	114.7	136.6	209.7	336.7
Overseas Orders Ratio	10.5%	12.3%	12.9%	20.6%	28.6%	42.9%

(Note) Results of Ina Research are included from the first half of the fiscal year ending March 31, 2023.  
 For calculation of Contracts Received (Overseas), an average USD/JPY exchange rate of each fiscal year is applied.  
 For calculation of Backlog (Overseas), a year-end exchange rate of each fiscal year is applied.

# CRO Business: Contracts Received (Overseas) in Nonclinical Business in 1H FY2023/3



(Note) Results of Ina Research are included from the first half of the fiscal year ending March 31, 2023.

# CRO Business: Initiatives in Response to the Increasing Demand for NHP Studies

## Current Situation

The worldwide shortage of NHPs for biomedical research still continues, however, we have not experienced any adverse influence when conducting NHP studies due to our distinguished NHP supply chain that has uniquely been established from 1990's.

## Further Enhancements of NHP Supply Chain

- Increasing the breeding capacity in our Cambodian facility and enhancing NHP procurement routes
- Increasing and enhancing the breeding capacity within Japan facility

## Increase in Capacity for Study Conduct

- Increased the capacity of study rooms compliant with the EU standard in response to the growing demand from Western clients who have more strict animal welfare requests (completed in 2Q).
- Increasing more study rooms to be completed during early 4Q in FY23/3.

# CRO Business: Investments for Our Future Growth

## To meet the growing demand from our clients:

### 1. Enhance the Analytical Capability/Capacity

- In response to the active global development of multiple drug modalities
- New state-of-the-art instruments were introduced, and the lab space was expanded in this 3Q.

### 2. Construct New 8-story building in Kagoshima Site

- Initiates in 3Q of FY23/3, and expects to complete in summer in 2024

### 3. Recruiting New Employees

- Enhancing the recruiting activities for new graduates and for experienced researchers in the industry



# 3. Business Topics : CRO(Clinical)/TR/Medipolis Businesses

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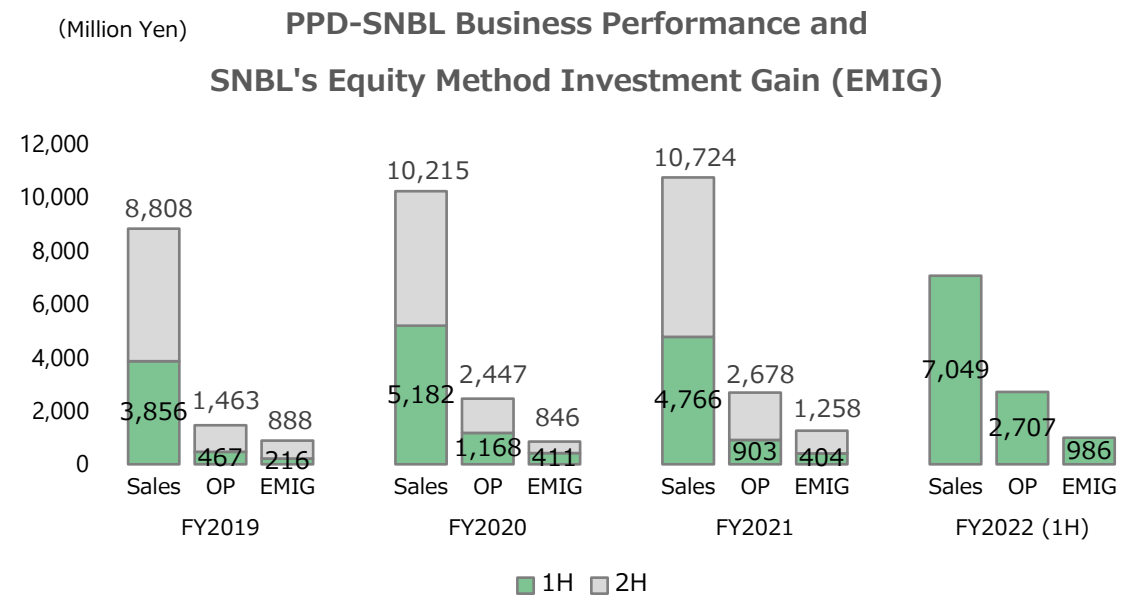
Ken Takanashi, MBA, CPA  
Executive Vice President



Ichiro Nagata, MD, PhD, MMH, MBA  
Executive Director

# I . CRO (Clinical) Business

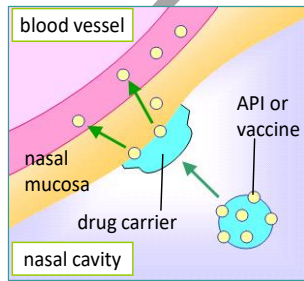
- **In the midst of overcoming the global challenge of pandemics, the importance of global clinical trials has been increasing in recent years to improve cost efficiency while overcoming medical drug lag**
- Our partner, PPD Group, has been steadily growing its business as a highly reliable global CRO with the capability to conduct simultaneous clinical trials in approximately 50 countries. Thermo Fisher Scientific, one of the world's leading medical device companies has acquired the PPD Group to develop a global strategy of full-line services. This acquisition is expected to have a synergistic effect on order acceptance by mutually complementing the customer networks of PPD Group and Thermo Fisher Scientific.
- PPD-SNBL K.K. is the sole joint venture of PPD Group and SNBL owns 40% of its stocks. PPD-SNBL K.K. has developed its organization by incorporating elements of Japanese management, which gives strength to increase its global clinical study contracts.
- The company is receiving orders for studies in areas that meet recent development needs, such as malignant tumors, infectious diseases, central nervous system, cardiovascular system, and metabolism/endocrine system. In response to the steadily growing order, the company is strengthening its human resources.



# II. TR Business

## -SNBL Nasal Drug Delivery Platform Technology and Its Applications

### SNBL's Proprietary Nasal Drug Delivery System



#### Nasal Drug Carrier

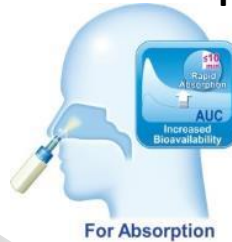
- ✓ Muco-adhesive power carrier and specific optimizations for each drug characteristic
- ✓ Clinical and non-clinical experiences with candidate products for the systemic absorption

#### Nasal Delivery Device

- ✓ User-friendly
- ✓ Light-weight and compact
- ✓ Complete and consistent delivery
- ✓ Low cost
- ✓ Specific design for each nasal application

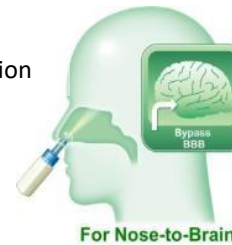


#### For Systemic Absorption



- Drug absorption via the dense microvascular network
- Beneficial for any treatment requiring fast onset of action or bypass of first-pass metabolism, and for patients with difficulty swallowing oral medication
- Excellent clinical safety profile in thousands of subjects
- Out-licensed the nasal migraine drug to Satsuma Pharm.
- SNLD, Ltd., a spin-out subsidiary of SNBL, completed its clinical P1 study for the candidate rescue product for neurodegenerative disorder. The clinical study data is under analysis.

#### For Nose-to-Brain Delivery



- Drug delivery directly from the olfactory region to the brain
- Beneficial technology for drugs which are do not or difficult to pass the BBB
- Reduce systemic toxicity
- Exploring drug candidates for development

#### For Vaccination

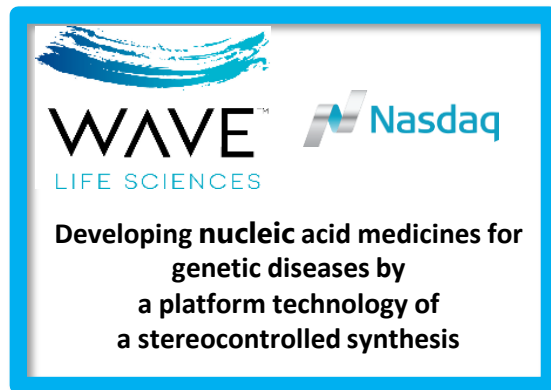


- First-line defense with mucosal immunity
- Second-line defense with systemic immunity
- Cross protection (protection against mutant strains)
- Preparing for an experimental study targeting at respiratory infectious diseases, such as COVID-19 and influenza

## II . TR Business -Important investees-



- Established in the U.S. in June 2016 as a licensee of SNBL proprietary nasal drug delivery technology with limited application for nasal migraine drug (DHE)
- Listed on Nasdaq in September 2019, raising funds mainly from U.S. institutional investors]
- Completed subject enrollment in its Phase 3 clinical (drug efficacy) study in August 2022 and the clinical study data will be published by the end of the year (NDA submission is planned in the 1Q of 2023)
- Income from license (royalties on sales) expected after the launch on the market
- SNBL owns 8.4% of the company stocks.



- Spin-out from the company established in Singapore in 2012 which was integrated from a SNBL subsidiary in the U.S. established in 2009 with a professor from Harvard University, and the one in Japan established in 2008 with a professor from the University of Tokyo
- Listed on Nasdaq in November 2015, raising funds mainly from US institutional investors
- Clinical trials for three programs (Huntington's disease, ALS/FTD, and Duchenne muscular dystrophy) by the latest stereocontrol synthesis technology has been underway since 2021
- A development program utilizing its own genome editing (ADAR) technology (AATD) is also underway
- Increased its capital by US\$70 million in June 2022 and promoting in-house clinical study programs and GMP manufacturing capabilities
- SNBL owns 10.6% of the company stocks.

## II . TR Business: Business Overview

### Business Development Platform

- Gemseki mediates drug and delivery technology candidates between in and out-licensors globally and supports a smooth and efficient drug development.

### Venture Capital Investment

- In addition to our business development platform, we act as a developmental partner of domestic and international clients who are committed to their growth and success within the life science business with investment and business incubation system.
- We can support by using an abundant drug development experience and a strong global network within the SNBL Group.

Name	Gemseki Investment Limited Partnership
Fund Total	1.1 Billion JPY
Operation Period	10 years
Establishment	August, 2020
Target and Policy	We widely target within the drug development and healthcare field from drug candidates to early, middle, and later stages.

**Support system to investee company**

## Ⅲ. Medipolis Business – Hospitality (AMAFURU & Co.)

At AMAFURU & Co., we are involved in facility management within Wellness Resort Medipolis Ibusuki. As the affinity of the group as a whole, we operate 3 hotel business with our main concept as “Wellbeing of the People”; in other words, the realization of the overall health.

### Healing Resort AMAFURU

We provide Japanese hospitality to guests with the 3 pillars of wellness, nature, and luxury.



### Retreat Resort Ibusuki Bayhills

With the concept of “A second house within nature”, we provide a retreat and workcation service to look back at yourself.



### Medical Resort HOTEL Fresia

We provide a comfortable and relaxing environment for patients receiving treatment at the Medipolis Proton Therapy and Treatment Center and their family.



Medipolis Medical Research Institute  
Medipolis Proton Therapy and Research Center

# Ⅲ. Medipolis Business – Sustainable Development Company ~Toward the Achievement of SDGs~

## ■ Geothermal Power Generation



### <Main advantages of geothermal power generation>

1. Nearly zero CO2 emission and excellent environmental compatibility
2. A base-load power source capable of stable power generation
3. Japan has the third largest amount of worldwide geothermal power resources
4. Multi-stage energy utilization (e.g. the use of hot water after power generation)

Increasing demand of geothermal power generation is expected toward the Japanese government's goal of achieving carbon neutrality by 2050.

【Geothermal Power Plant in Medipolis Ibusuki】

- Our binary geothermal power plant rated at 1,580 kW has been operating since February 2015.
- All of the generated electricity is sold under the FIT Law, providing us a stable income.
  - Average operating income (as power generation division): 182 million yen
  - Average sales of electricity per annum (average over the past 3 years): 10,471k kWh\*(\*Approx. 55% of our annual power consumption)
  - Average equipment utilization rate (average for the past 3 years): 75.7%
- Surplus steam from the power plant is used for greenhouse cultivation, heating of swimming pools, and heating of facilities, reducing CO2 emissions through multi-stage energy utilization.
- In June 2022, we finished constructing a system of geothermal power generation by the hot spring water currently used for bathing at our hotel. We aim the system sell its electricity within this year.
- Planning a joint study with a University to investigate the possibility of CCS (Carbon Dioxide Capture and Storage) within our site.

## ■ Seedling Production of Glass Eels

- We conduct 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).

# Q&A

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# Cautionary Notes

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 Six Months of the Fiscal Year Ending March 31, 2023 (Japanese GAAP)." Figures rounded to the nearest 100 million JPY 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.

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I am happy, you are happy, and everyone is happy.



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