

# The Fiscal Year Ended March 31, 2022 Financial Results Presentation

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May 10, 2022



SHIN NIPPON BIOMEDICAL LABORATORIES, LTD.

(TSE PRIME: 2395)



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# 1. FY2022/3 Overview & Future Outlook

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Ryoichi Nagata, MD, PhD, FFPM

Representative Chairman and President, CEO and CHO

# Summary



## 1. FY2022/3 Results

- Various measures and management efforts finally starting to pay off and bear fruit
- Achieved double-digit increase in revenue and profits, driven by the industry-wide trend of accelerating R&D activities targeting new drug modalities
- Realized record-high profits, orders received and dividend

## 2. FY2023/3 Forecasts & Future Direction

- Expect two-digit growth in revenue and profit as favorable business environment continues
- Promote “time-value creation” that help maximize benefits in clients by leveraging DX and robotization
- Launch P1 clinical trial for proprietary nasal drug delivery platform technology
- Plan over ¥5 bn investment in facilities this fiscal year to further accelerate our sustainable growth

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

- Focus on employees’ happiness: improvement of compensation system, better disclosure of promotional eligibility, and promotion of job satisfaction reform, etc.
- Selected for Nadeshiko Brand 2021 for the 1<sup>st</sup> time and for Health & Productivity Management Outstanding Organization (large enterprise category (White 500)) for the 6<sup>th</sup> consecutive year.
- Aim to realize “Carbon-Neutral” by 2030, by leveraging a vast land and forest in Medipolis Ibusuki, Kagoshima
- Plan to publish the first Integrated Report which brings together SNBL’s material financial/nonfinancial information this autumn.



June, 2011 Full AAALAC Accreditation

# Initiatives to Enhance Corporate Value : SDGs/ESG

<Materiality and Sustainability Focus at SNBL Group>



■ Forest in Medipolis Ibusuki, Ibusuki City, Kagoshima Pref.



■ Geothermal power plant in Medipolis Ibusuki

<Corporate Philosophy>

We are a company that values the environment, life, and people.

<SNBL Corporate Slogan>

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

Source : "Sustainability Report 2021" (<https://www2.tse.or.jp/disc/23950/140120211025416124.pdf>)

## 2. Outline of Full-Year Consolidated Financial Results

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Shinji Nitanda  
Senior Managing Executive Officer and CFO

# FY2022/3 Financial Results Highlights

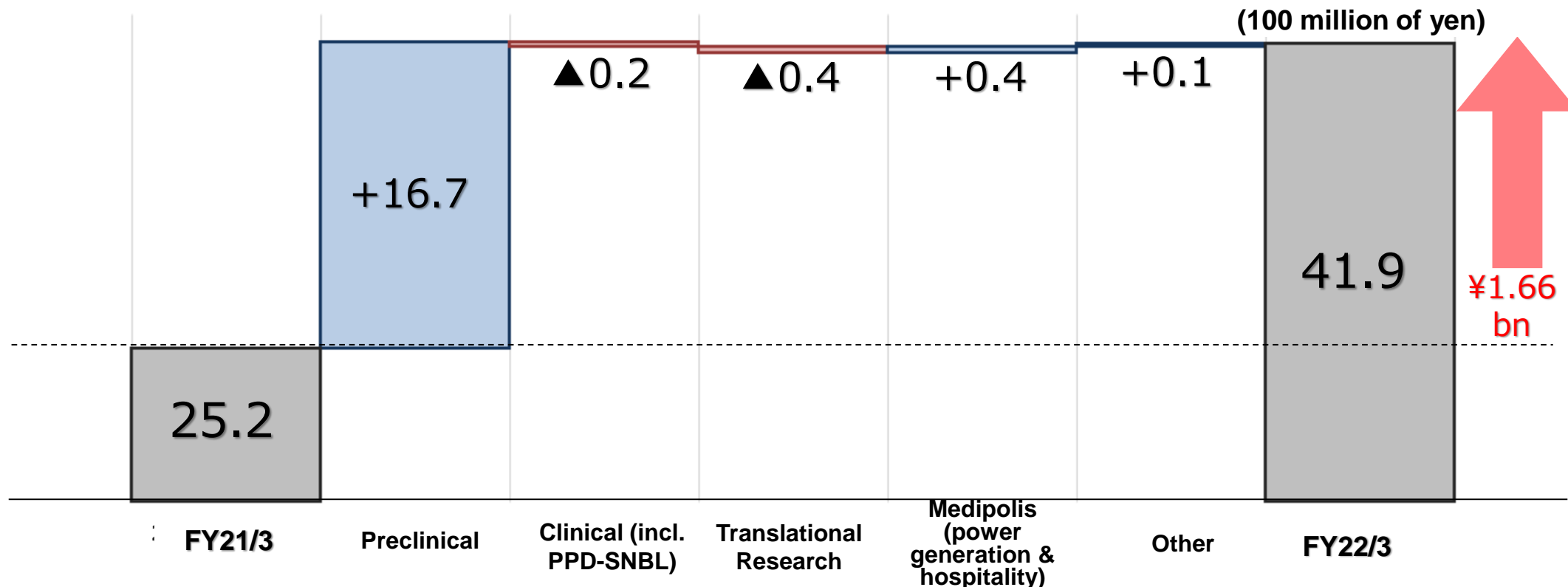
**Record high profits achieved** at Operating Profit, Ordinary Profit and Profit Attributable to Owners of Parent. FX gains of JPY 1.37 bn resulted in Ordinary Profit significantly exceeded the forecasts announced on 2/2/2022.

(100 million of yen)

	FY2021/3 Results	FY2022/3				
		Previous forecasts (2/2/2022)	Results	Changes against previous forecasts	Yoy	
Net sales	151.1	179.0	<b>177.4</b>	<b>-1.5</b>	<b>+26.3</b>	<b>17.5%</b>
Operating Profit	25.2	41.0	<b>41.9</b>	<b>+0.9</b>	<b>+16.6</b>	<b>65.9%</b>
Ordinary Profit	36.4	56.3	<b>70.7</b>	<b>+14.4</b>	<b>+34.3</b>	<b>94.2%</b>
Ordinary Profit (excl. FX gain/loss)	34.0	51.3	<b>57.0</b>	<b>+5.6</b>	<b>+23.0</b>	<b>67.6%</b>
Profit Attributable to Owners of Parent	36.6	58.0	<b>71.2</b>	<b>+13.2</b>	<b>+34.6</b>	<b>94.6%</b>

# Yoy Comparison of Consolidated Operating Profit & Loss

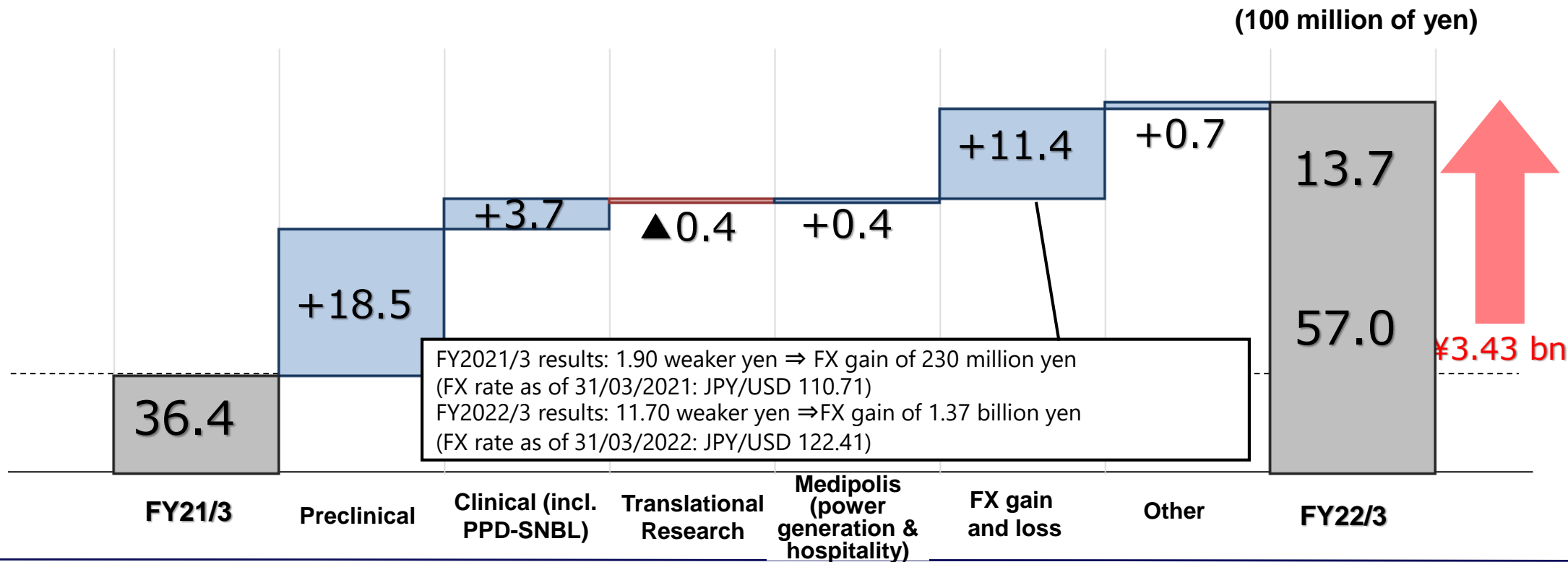
						Operating profit total
	CRO business		Translational Research business	Medipolis business (power generation & hospitality)	Other	
	Preclinical	Clinical (incl. PPD-SNBL)				
FY2022/3	51.0	0.7	-7.4	-0.1	-2.3	41.9
FY2021/3	34.3	0.9	-7.0	-0.5	-2.5	25.2
Yoy changes	+16.7	-0.2	-0.4	+0.4	+0.1	+16.6





# Yoy Comparison of Consolidated Ordinary Profit & Loss

	CRO business		Translational Research business	Medipolis business (power generation & hospitality)	Foreign exchange gain and loss	Other	Ordinary profit total
	Preclinical	Clinical (incl. PPD-SNBL)					
FY2022/3	52.8	13.7	-7.4	-0.1	13.7	-2.0	70.7
FY2021/3	34.3	10.0	-7.0	-0.5	2.3	-2.7	36.4
Yoy changes	+18.5	+3.7	-0.4	+0.4	+11.4	+0.7	+34.3



# FY2023/3 Forecasts

**Record high** Operating Profit for the fourth consecutive year expected.  
Excluding FX impact, positive growth of Ordinary Profit is also in projection.

(100 million of yen)

	FY2021/3 Results	FY2022/3 Results	FY2023/3		
			Full-year Forecasts	Changes against previous forecasts	
Net sales	151.1	177.4	<b>196.0</b>	<b>+18.5</b>	<b>10.4%</b>
Operating Profit	25.2	41.9	<b>50.0</b>	<b>+8.0</b>	<b>19.2%</b>
Ordinary Profit	36.4	70.7	<b>60.0</b>	$\Delta$ <b>10.7</b>	<b>-15.2%</b>
Ordinary Profit (excl. FX gain/loss)	34.0	57.0	<b>60.0</b>	<b>+2.9</b>	<b>5.1%</b>
Profit Attributable to Owners of Parent	36.6	71.2	<b>43.0</b>	$\Delta$ <b>28.2</b>	<b>-39.7%</b>

<FY2023/3 forecasts keypoints>

1. Preclinical CRO business

Sales and profits are expected to increase by ¥1.76 bn and ¥1.29 bn respectively, yoy.

2. TR business

Spending on a clinical study for a nasal neurodegenerative disease rescue medication is planned.

3. FX gain and loss (non-operating profit/loss)

In relation to loans to subsidiaries, FX valuation decrease of ¥1.37 bn yoy is expected:

- FY2022/3 +¥1.37bn
- FY2023/3 ±¥0
- FX assumption: JPY/USD122.41

cf. FX sensitivity – 1 yen fluctuation

Sales: 44 million JPY/USD  
Operating Profit: 30 million JPY/USD  
Non-operating Profit: 120 million JPY/USD

4. Extraordinary profit

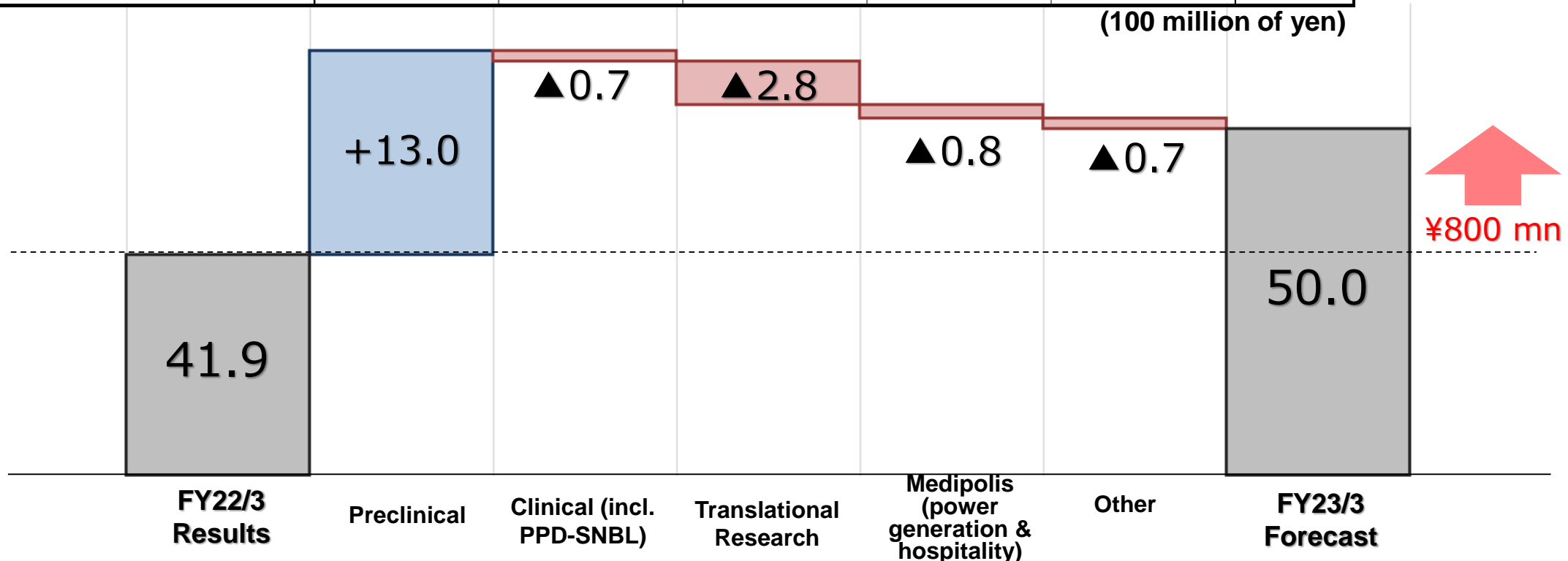
In FY2022/3, an extraordinary profit of ¥1.36 bn from change in equity in a subsidiary in China was recorded.

5. Corporate tax

Decrease of retained losses will result in less tax shield.

# Comparison of FY2023/3 Consolidated Operating Profit & Loss Forecasts against FY2022/3 Results

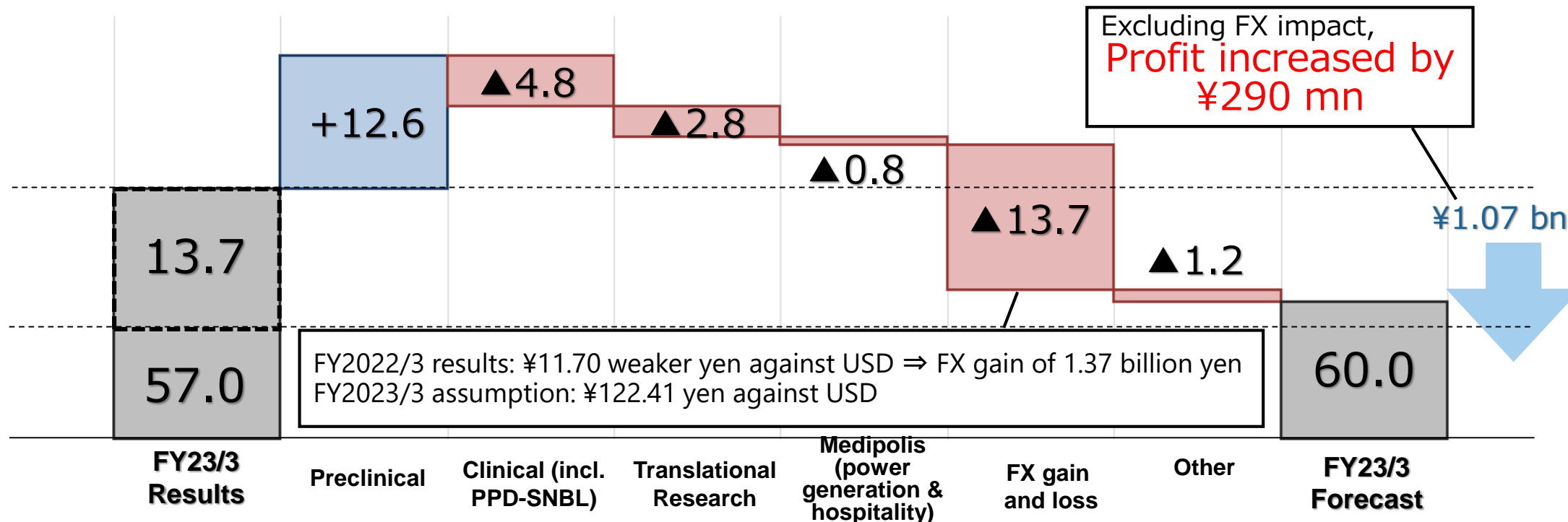
	Operating Profit Components					Operating profit total
	CRO business		Translational Research business	Medipolis business (power generation & hospitality)	Other	
	Preclinical	Clinical (incl. PPD-SNBL)				
FY2023/3 forecast	64.0	0.0	-10.2	-0.9	-2.9	50.0
FY2022/3 results	51.0	0.7	-7.4	-0.1	-2.3	41.9
Yoy changes	+13.0	-0.7	-2.8	-0.8	-0.7	+8.0



# Comparison of FY2023/3 Consolidated Ordinary Profit & Loss Forecasts against FY2022/3 Results

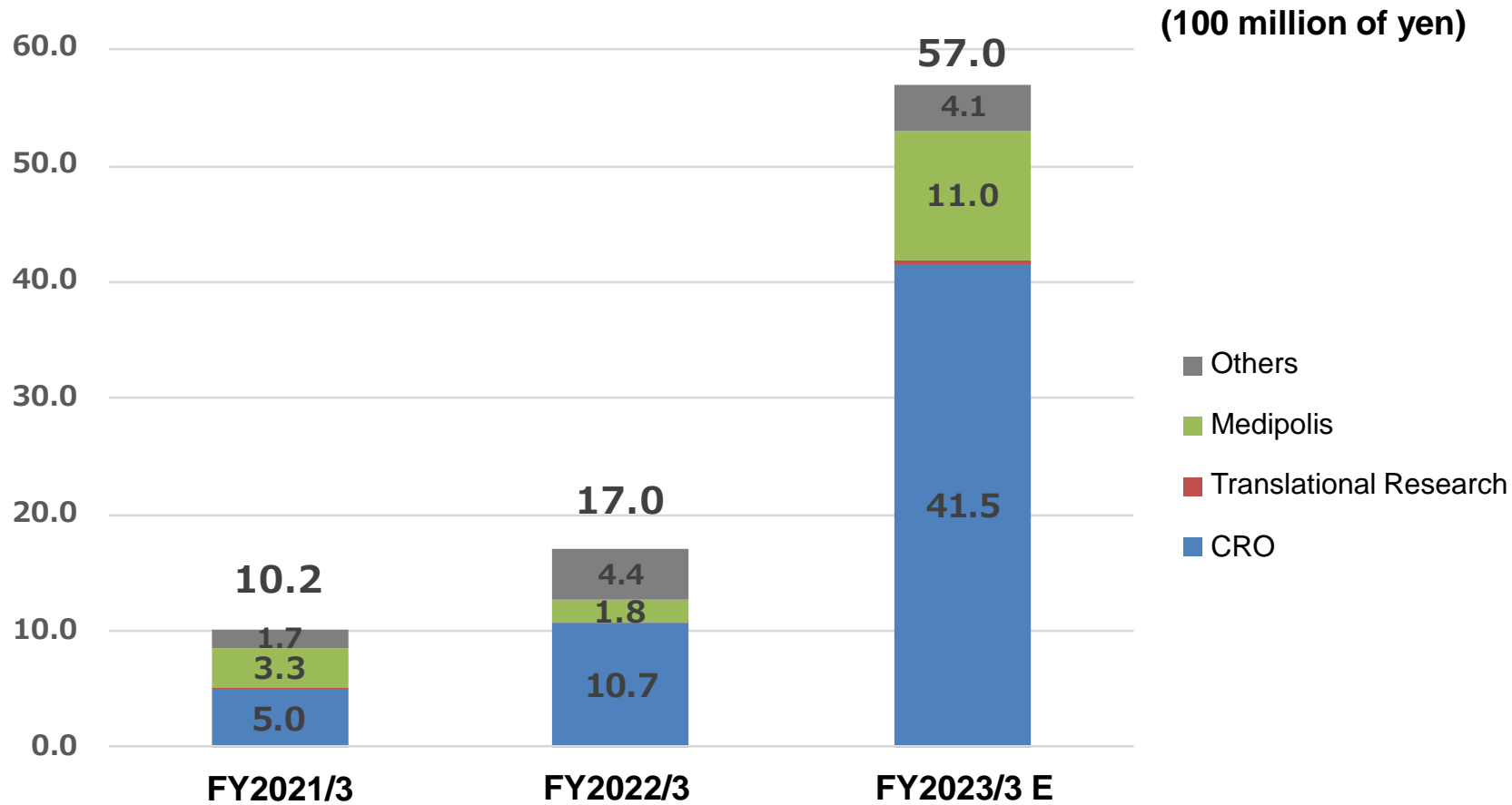
	CRO business		Translational Research business	Medipolis business (power generation & hospitality)	Foreign exchange gain and loss	Other	Ordinary profit total
	Preclinical	Clinical (incl. PPD-SNBL)					
<b>FY2023/3 forecast</b>	<b>65.4</b>	<b>8.9</b>	<b>-10.2</b>	<b>-0.9</b>	<b>0.0</b>	<b>-3.2</b>	<b>60.0</b>
FY2022/3 results	52.8	13.7	-7.4	-0.1	13.7	-2.0	70.7
Yoy changes	+12.6	-4.8	-2.8	-0.8	-13.7	-1.2	-10.7

(100 million of yen)



# CAPEX

**CRO (preclinical) Business and Medipolis (power generation) Business will be key focus areas in FY2023/3.**



	FY2021/3	FY2022/3	FY2023/3	
			Forecasts	Yoy
CAPEX	10.2	17.0	57.0	+40.0
Depreciation	11.8	11.7	14.1	+2.4

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

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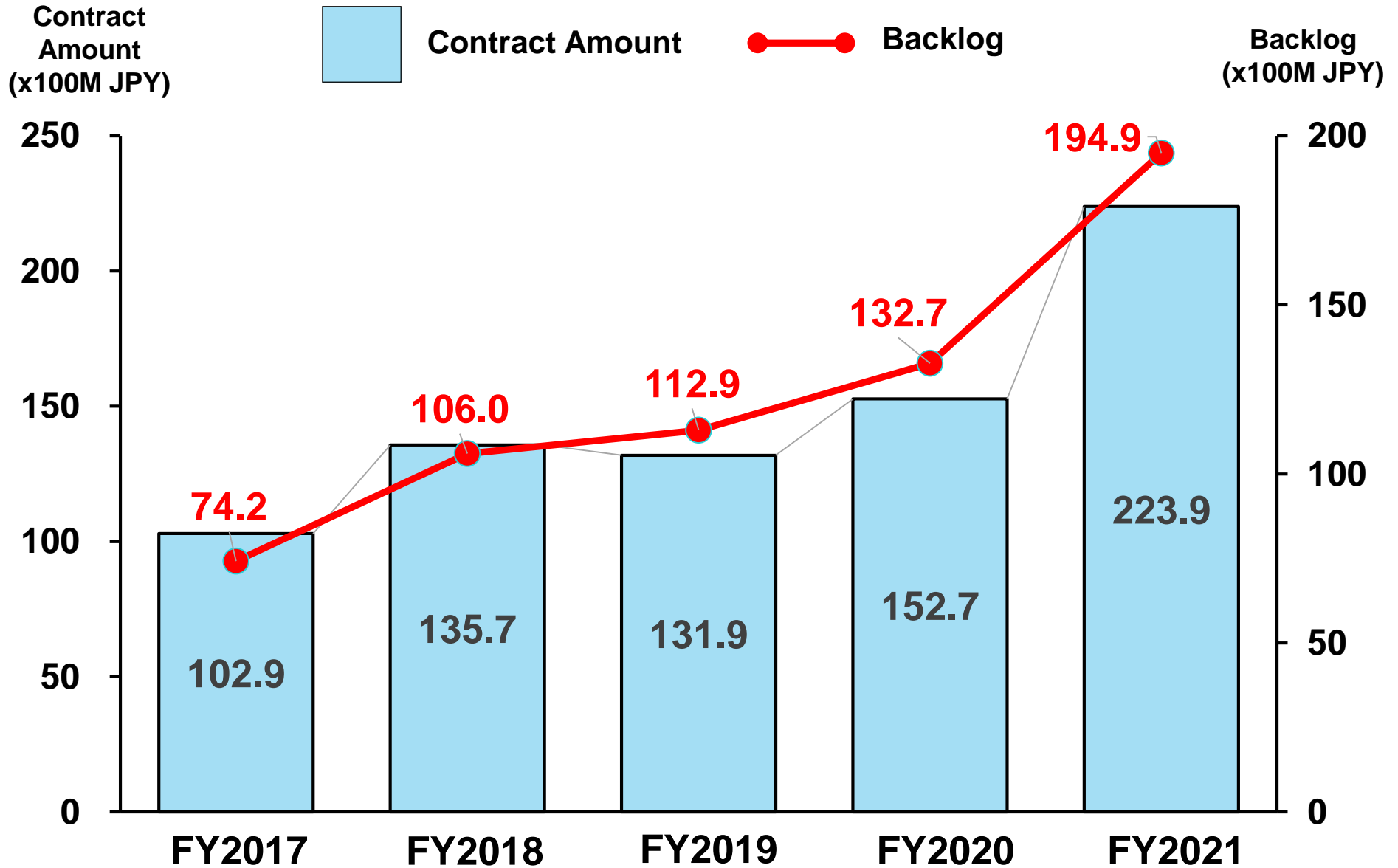


Hideshi Tsusaki, DVM, PhD

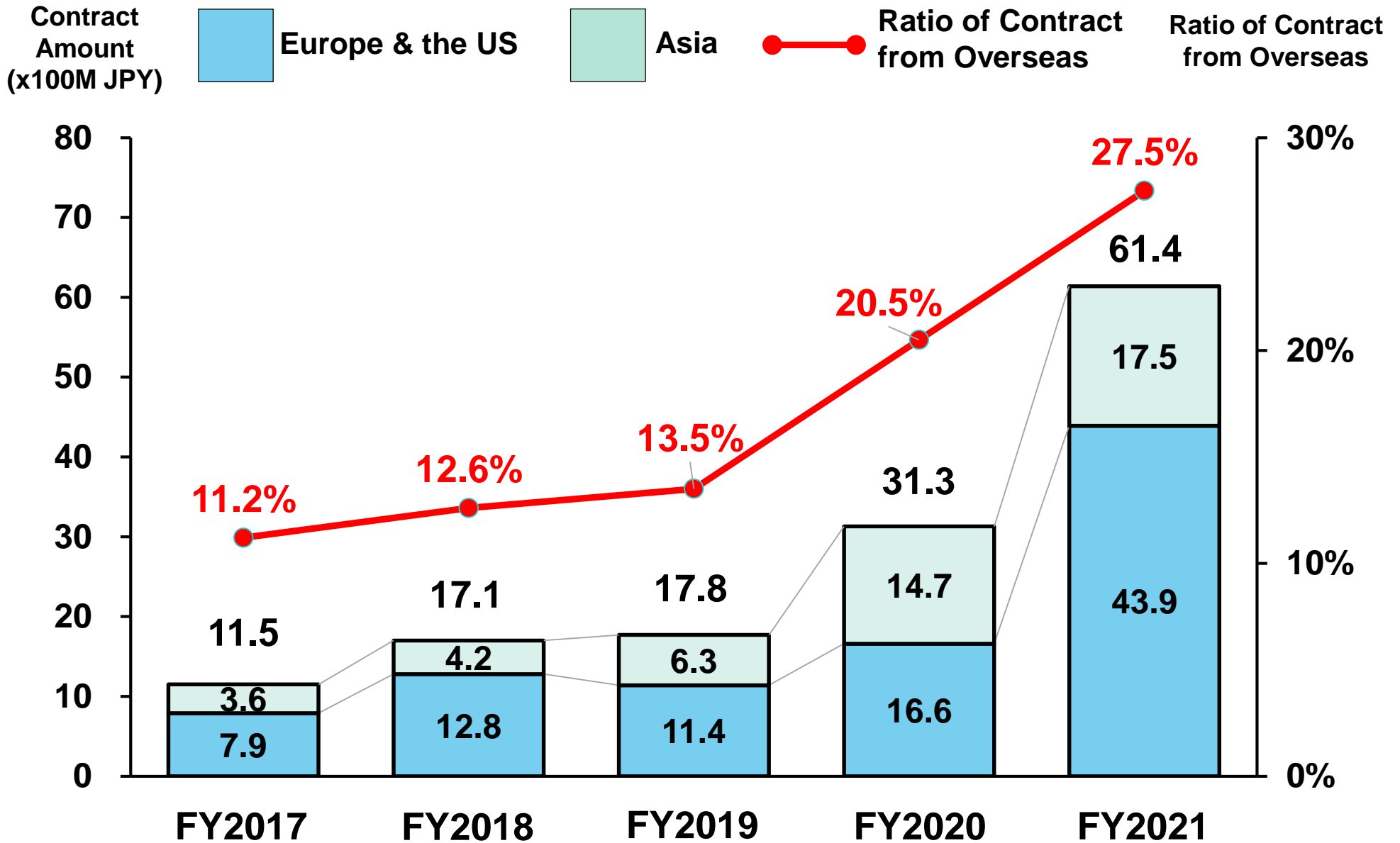
Senior Executive Director,

President of Preclinical Business and Global BD

# CRO Business: Contract



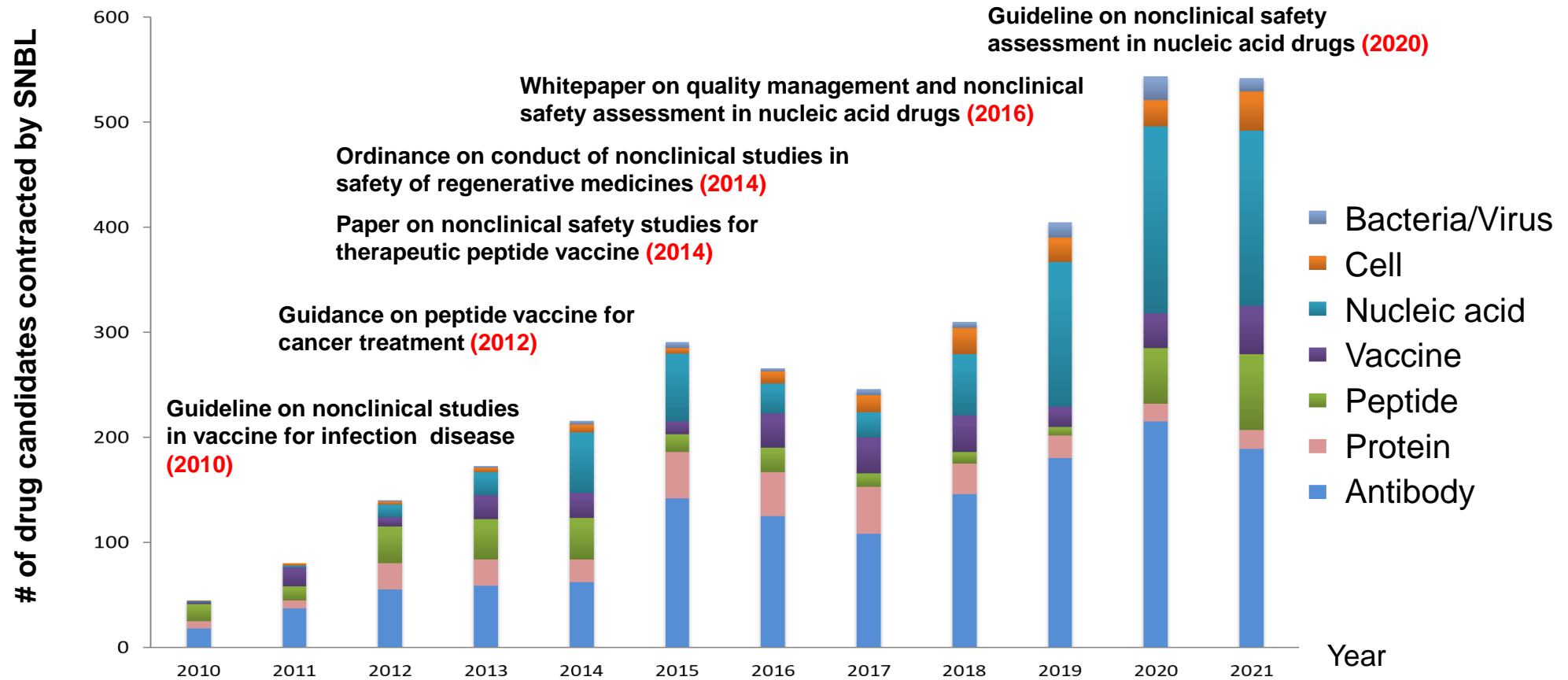
# CRO Business: Contract from Overseas





# CRO Business: Contract by drug modality

- Number of drug candidates contracted (excluding low molecules)
  - Number in 2021 was almost equal to that in 2020. An increase in vaccine and peptide was noted.
- Number of studies in drug candidates contracted (excluding low molecules)
  - Number of studies (719) in 2021 increased by 43% compared with that in 2020. Number of GLP studies (253) in 2021 increased by 51%. An increase in antibody and nucleic acid was noted.



# CRO Business: Our Strength in NHP studies

## Distinguished NHP Supply Chain

- Our own control in breeding, raising, transporting, and stably assigning to a study within the SNBL Group
  - The business model that we uniquely established from 1990's at the first time in the globe

## Worldwide Shortage of NHPs due to Covid-19 Pandemic

- Active global development of multiple drug modalities (Increase in demand)
- Continuing suspension of NHP exports from the dominant supply country, China (limitation in supply)
  - No adverse influence in SNBL because of our established own supply chain

## Further Enhancements of the NHP Supply Chain and of Capacity in Study Conduct

- Increasing the breeding capacity in our Cambodian facility and enhancing NHP procurement routes
- Increasing and enhancing the breeding capacity within Japan facility
- Adding the research facility including NHP study rooms and actively recruiting research staff

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

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Ken Takanashi, USCPA  
Executive Vice President and COO

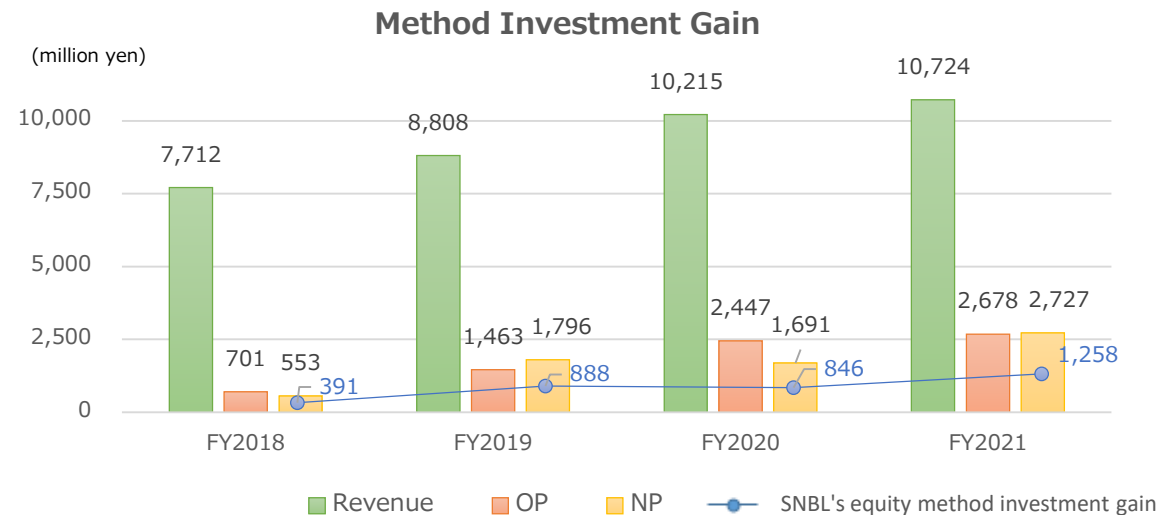


Ichiro Nagata, MD, PhD, MMH, MBA  
Executive Director

# 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., which SNBL owns 40% of its stocks and the sole joint venture of PPD Group, has achieved a high employee retention rate by incorporating elements of Japanese management and has expanded its business. (After 4 years of its establishment, it was selected as one of the top 5 growing companies to attract workers in 2019 by Randstad Japan)
- 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.

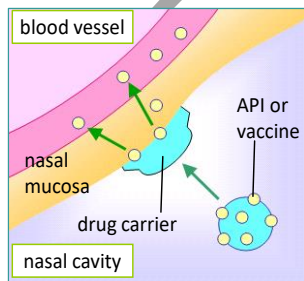
PPD-SNBL Business Performance and SNBL's Equity



# II .TR Business

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

### SNBL's Proprietary Nasal Drug Delivery System



#### Nasal Drug Carrier

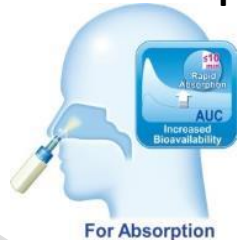
- ✓ Muco-adhesive power carrier and specific optimizations for each drug characteristic
- ✓ Clinical and non-clinical experiences with candidate products for the systemic absorption

#### Nasal Delivery Device

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

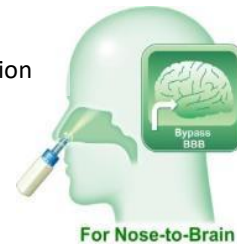


#### For Systemic Absorption



- 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.
- On-going clinical P1 study for the candidate rescue product for neurodegenerative disorder by SNLD, Ltd. a spin-out subsidiary.

#### 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

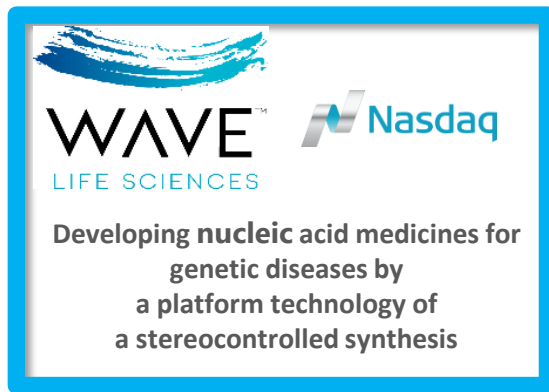


- First-line defense with mucosal immunity
- Second-line defense with systemic immunity
- Cross protection (protection against mutant strains)
- Aiming to demonstrate ideal application to respiratory infectious diseases. Such as COVID-19 and influenza.

## 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]
- Currently conducting Phase 3 pivotal study (efficacy/safety) in the U.S. (NDA submission is planned in the 1Q of 2023)
- Income from license (royalties on sales) expected after launch
- SNBL owns 8.9% 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
- Commercialization, including partnering, is being considered to utilize in-house GMP manufacturing capabilities.
- SNBL owns 9.1% 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

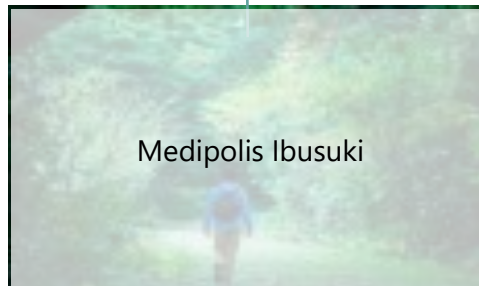
- In addition to our business development platform, we act as a developmental partner of domestic and international clients who are committed to their growth and success within the life science business with investment and business incubation system.
- We can support by using an abundant drug development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



HOTEL Fresia



Medipolis Medical Research Institute  
Medipolis Proton Therapy and Research Center

## 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.



# 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.
- We are working on geothermal power generation by the hot spring water currently used for bathing at our hotel. We aim the system to start functioning 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).

# 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 Fiscal Year Ended March 31, 2022 (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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