

# First Quarter of Fiscal Year Ending March 31, 2024

## Consolidated Financial Results

Supplementary Material

**August 2, 2023**



SHIN NIPPON BIOMEDICAL LABORATORIES, LTD.

# Business Overview

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Toshiyuki Iwata,  
Managing Executive Director 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)

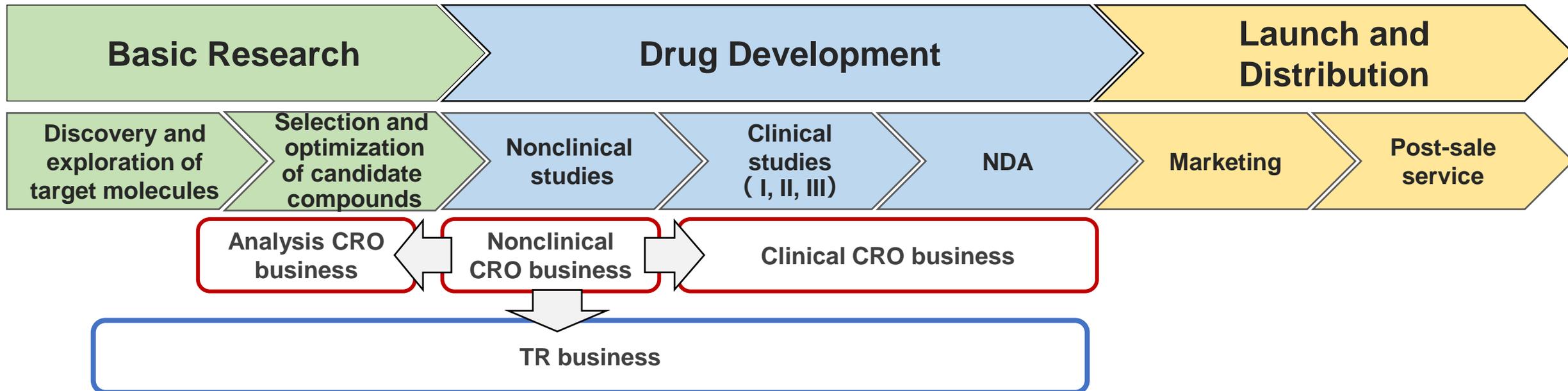
Foundation: September 16, 1957 (Incorporation: May 1973)

HQ location: Kagoshima City, Kagoshima Pref.

Main business: Contract Research Organization (CRO) business

Number of employees: 1,208 (as of 31/3/2023) Female ratio: 53.5% Foreign employee ratio: 15.1%

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



# Business Segments



3 reportable operating segments: CRO (Nonclinical and Clinical) business, Translational Research (TR) business, and Medipolis business (Social Benefits Generation business)

## Revenue and OP by Segment

		2021/3	2022/3	increase	2023/3	increase
CRO business	Revenue	14,508	17,047	17.5%	24,000	40.8%
	OP	3,393	5,035	48.4%	6,336	25.8%
	OP margin	23.4%	29.5%		26.4%	
	The share of profit of entities accounted for using equity method	848	1,438		2,489	
	Business Profit	4,241	6,473	71.2%	8,825	36.3%
	<b>Business Profit margin</b>	<b>29.2%</b>	<b>38.0%</b>		<b>36.8%</b>	
TR business	Revenue	12	12		16	
	OP	-708	-746		-879	
Medipolis business	Revenue	552	563		683	
	OP	-54	-17		-203	
Other	Revenue	503	968		1,437	
	OP	-35	41		110	
Adjustments	Revenue	-466	-844		-1,047	
	OP	-65	-116		-118	
Total	Revenue	15,110	17,748	17.5%	25,090	41.4%
	OP	2,529	4,195	65.9%	5,245	25.0%
	OP margin	16.7%	23.6%		20.9%	

## Q1 Revenue and OP by Segment

		2022/3 Q1	2023/3 Q1	2024/3 Q1	increase
CRO business	Revenue	2,876	3,679	5,616	52.6%
	OP	638	864	1,456	68.4%
	OP margin	<b>22.2%</b>	<b>23.5%</b>	<b>25.9%</b>	
	The share of profit of entities accounted for using equity method	192	366	531	44.9%
	Business Profit	830	1,230	1,987	61.5%
	<b>Business Profit margin</b>	<b>28.9%</b>	<b>33.4%</b>	<b>35.4%</b>	
TR business	Revenue	-	11	1	
	OP	-144	-123	-245	
Medipolis business	Revenue	136	175	196	
	OP	18	19	-6	
Other	Revenue	134	500	238	
	OP	-6	4	39	
Adjustments	Revenue	-106	-319	-248	
	OP	-13	-51	-16	
Total	Revenue	3,041	4,046	5,804	43.5%
	OP	491	714	1,227	71.9%
	OP margin	16.1%	17.6%	21.1%	

\* Business Profit = OP + The share of profit of entities accounted for using equity method

# Outline of Q1 FY2024/3 Consolidated Financial Results

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# Q1 FY2024/3 Consolidated Financial Results Highlights



**Record-high revenue** posted thanks partly to Ina Research's contribution of revenue of ¥1.07B contribution. Overseas revenue increased to ¥2.35B, almost fourfold growth YoY. **Operating profit marked a record-high** double-digit growth as overseas revenue increased while revenue from exclusive colony services and large-scale projects from domestic client originally-planned in Q2 were recorded ahead of schedule in Q1. These key factors offset increased labor costs and those related to study materials. Ordinary profit decreased by ¥0.89B YoY mainly due to a less contribution of foreign currency gain which decreased by ¥1.4B to ¥0.28B YoY from ¥1.68B in the same period previous year. Excluding FX impacts, ordinary profit increased by 46.4% YoY. **Profit attributable to owners of parent** increased by ¥0.2B YoY to ¥0.55B and **marked a record-high growth**.

(Units: JPY100M)

	FY2024/3		
	Results	YoY changes	
Revenue	<b>58.0</b>	+17.5	+ 43.5%
Operating Profit	<b>12.2</b>	+5.1	+ 71.9%
Ordinary Profit	<b>18.7</b>	-8.9	-32.3%
Ordinary Profit (excl. FX impact)	<b>15.8</b>	+5.0	+46.4%
Profit Attributable to Owners of Parent	<b>13.7</b>	-5.7	-29.4%

# YoY Comparison of Consolidated Operating P/L: Q1 FY2024/3

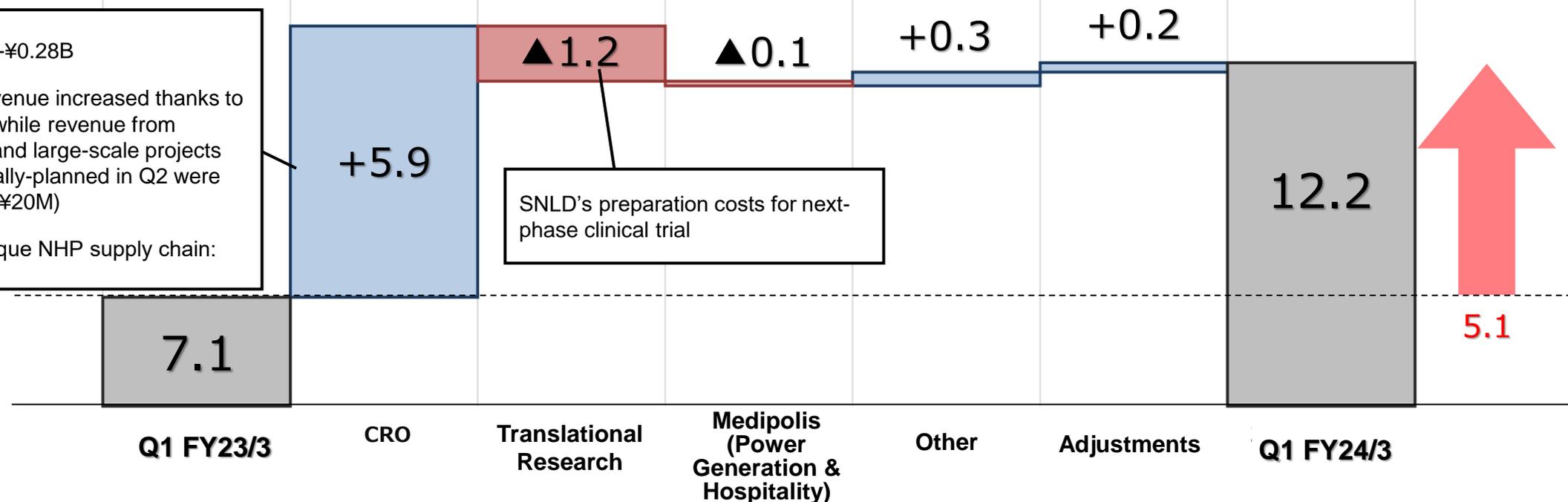
(Units: JPY100M)

	CRO Business	Translational Research Business	Medipolis Business (Power Generation & Hospitality)	Other	Adjustments	Operating Profit Total
<b>Q1 FY2024/3 Results</b>	<b>14.5</b>	<b>-2.4</b>	<b>0.0</b>	<b>0.3</b>	<b>-0.2</b>	<b>12.2</b>
Q1 FY2023/3 Results	8.6	-1.2	0.1	0.0	-0.4	7.1
YoY changes	+5.9	-1.2	-0.1	+0.3	+0.2	+5.1

<Operating Profit> +¥1.3B  
 Nonclinical CRO (Japan): +¥0.28B

Profitability of overseas revenue increased thanks to weaker yen against USD, while revenue from exclusive colony services and large-scale projects from domestic client originally-planned in Q2 were recorded. (Ina Research: +¥20M)

Contribution of SNBL's unique NHP supply chain: +¥0.31B

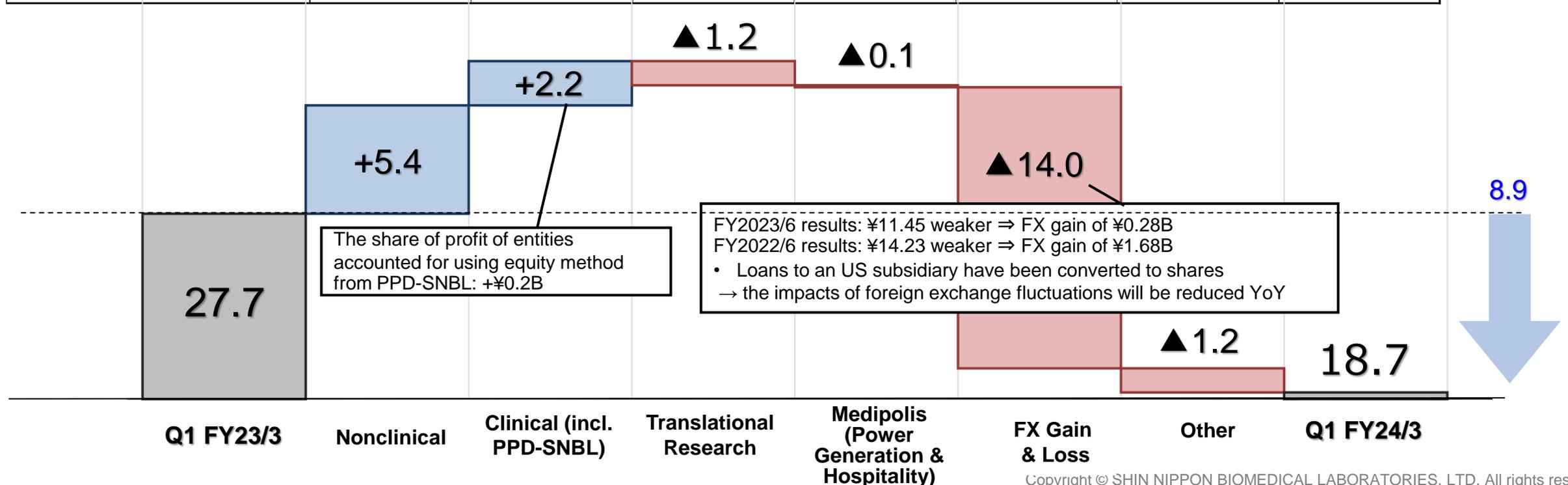


# YoY Comparison of Consolidated Ordinary P/L: Q1 FY2024/3



(Units: JPY100M)

	CRO Business		Translational Research Business	Medipolis Business (Power Generation & Hospitality)	Foreign Exchange Gain & Loss	Other	Ordinary Profit Total
	Nonclinical	Clinical (incl. PPD-SNBL)					
	<b>Q1 FY2024/3 Results</b>	<b>14.5</b>					
Q1 FY2023/3 Results	9.1	3.4	-1.2	0.1	16.8	-0.5	27.7
YoY changes	+5.4	+2.2	-1.2	-0.1	-14.0	-1.2	-8.9



# Financial Forecast Revision for FY2024/3

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# Financial Forecast Revision for H1 FY2024/3



Revenue is expected to undershoot the initial forecast announced on May 8, 2023, due mainly to carried-over studies in nonclinical CRO business which will be posted in the second half of the fiscal year. Operating profit will exceed the initial forecast and remain on a par with the first half of the previous year as labor costs and those for study materials are on the rise. Ordinary profit will also exceed the initial forecast thanks to PPD-SNBL's contribution. Negative growth compared to the same period of the previous year is expected due to less FY gains (¥2.29B decrease YoY) and acquisition costs of Satsuma Pharmaceuticals' shares (¥0.24B).

(Units: JPY100M)

	H1 FY2024/3				
	Forecast (Aug 2, 2023)	Changes against original forecast		YoY changes	
Revenue	116.6	-2.3	-1.9%	+13.1	+ 12.7%
Operating Profit	22.6	+4.2	+ 23.4%	-0.5	-2.3%
Ordinary Profit	34.0	+4.9	+ 17.2%	-25.2	-42.7%
Ordinary Profit (excl. FX impact)	31.1	+2.0	+ 7.2%	-2.3	-6.9%
Profit Attributable to Owners of Parent	22.8	+2.9	14.6%	-21.3	-48.4%

## Forecast Revision Summary

### 1. Revenue

Against initial forecast: -¥0.23B

→ A part of contracted studies in nonclinical business carried over to the second half of this fiscal year (-¥0.27B)

### 2. Operating Profit

Against initial forecast: +¥0.42B

→ A better profitability of overseas revenue thanks to a weaker yen against USD, additional contribution from exclusive colony services for clients, and various cost-cut efforts.

### 3. FX gain and loss (non-operating income and expenses)

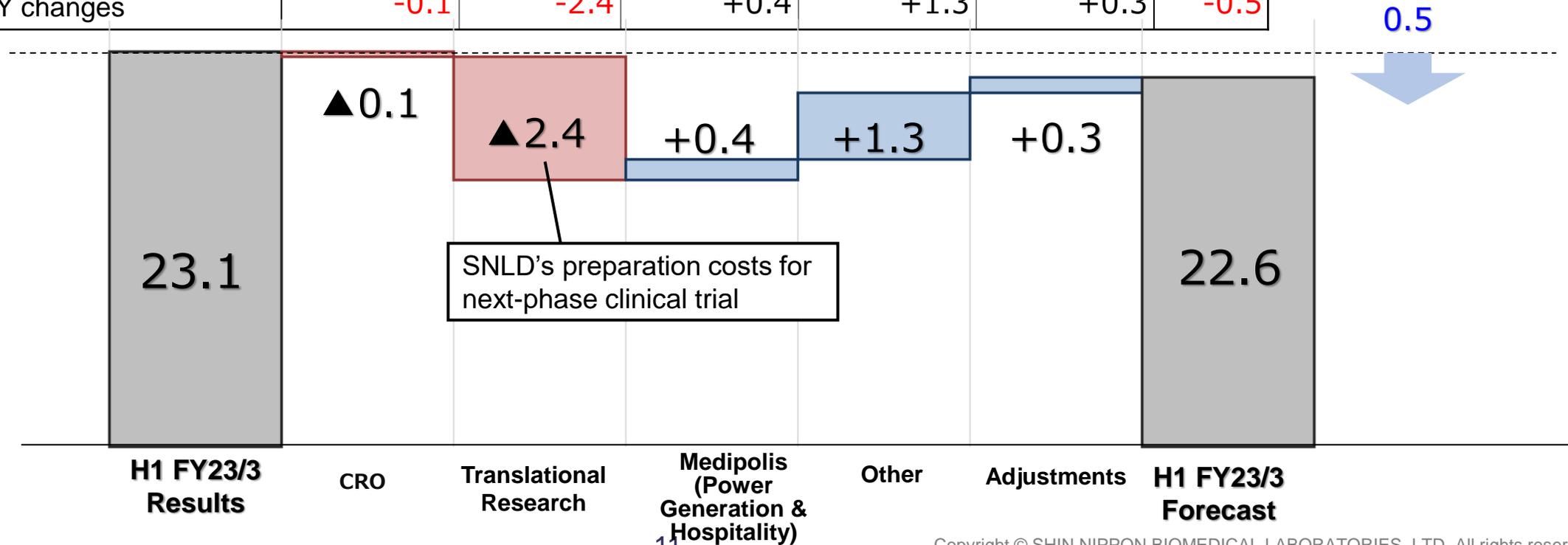
H1 forecast: +¥0.28B (originally zero)

→ A decrease by ¥2.29B from ¥2.58B in the same period of the previous year.

# YoY Comparison of Consolidated Operating P/L: H1 FY2024/3

	CRO Business	Translational Research Business	Medipolis Business (Power Generation & Hospitality)	Other	Adjustments	Operating Profit Total
H1 FY2024/3 Forecast	27.9	-5.6	-1.0	1.8	-0.5	22.6
H1 FY2023/3 Results	28.0	-3.2	-1.4	0.5	-0.8	23.1
YoY changes	-0.1	-2.4	+0.4	+1.3	+0.3	-0.5

(Units: JPY100M)

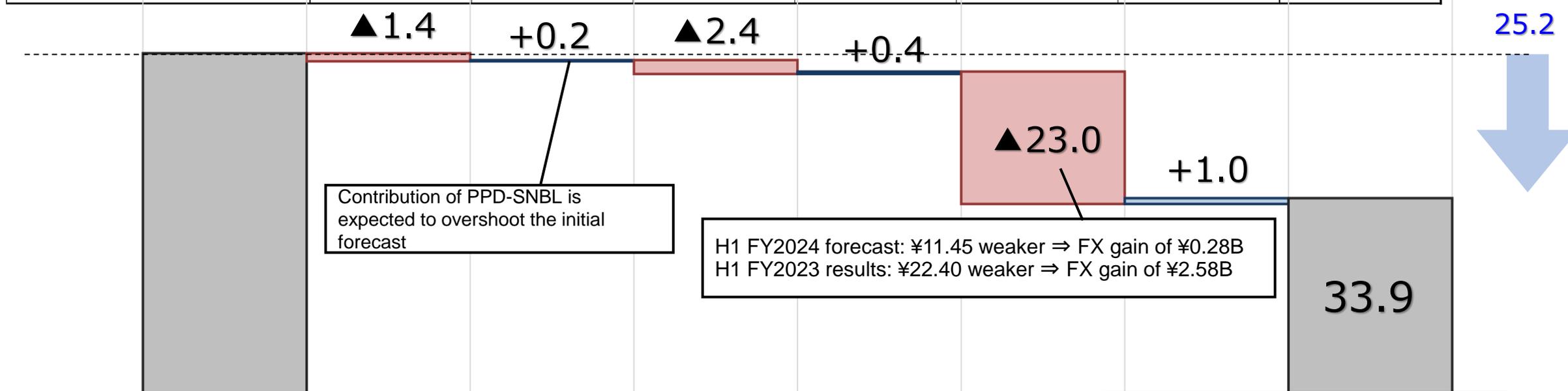


# YoY Comparison of Consolidated Ordinary P/L: H1 FY2024/3



(Units: JPY100M)

	CRO Business		Translational Research Business	Medipolis Business (Power Generation & Hospitality)	Foreign Exchange Gain & Loss	Other	Ordinary Profit Total
	Nonclinical	Clinical (incl. PPD-SNBL)					
H1 FY2024/3 Forecast	28.4	10.4	-5.6	-1.0	2.8	-1.1	33.9
H1 FY2023/3 Results	29.8	10.2	-3.2	-1.4	25.8	-2.0	59.2
YoY changes	-1.4	+0.2	-2.4	+0.4	-23.0	+1.0	-25.2



Contribution of PPD-SNBL is expected to overshoot the initial forecast

H1 FY2024 forecast: ¥11.45 weaker ⇒ FX gain of ¥0.28B  
 H1 FY2023 results: ¥22.40 weaker ⇒ FX gain of ¥2.58B

H1 FY23/3

Nonclinical

Clinical (incl. PPD-SNBL)

Translational Research

Medipolis (Power Generation & Hospitality)

FX Gain & Loss

Other

H1 FY24/3

# Financial Forecast Revision for Full-year FY2024/3



For the full-year forecast for FY2024/3, an assumed FX rate of ¥144.99/US\$ is applied to the initial forecast figures. If impacts of consolidation of Satsuma of \$11M (-¥1.59B) and FX gain/loss of ¥1.22B are excluded, we foresees to continue to grow YoY at all profits levels.

(Units: JPY100M)				
	FY2023/3	FY2024/3		
		Forecast (Aug 2, 2023)	YoY changes	
Revenue	250.9	<b>303.6</b>	+52.7	+ 21.0%
Operating Profit	52.4	<b>50.2</b>	-2.2	-4.3%
Ordinary Profit	91.9	<b>71.8</b>	-20.1	-21.9%
Profit Attributable to Owners of Parent	60.6	<b>47.8</b>	-12.8	-21.1%

Business Profit				
* excl. consolidation of Satsuma, FX impacts, and extraordinary gain/loss				
	FY2023/3*	FY2024/3*		
		Forecast (Aug 2, 2023)	YoY changes	
Revenue	250.9	<b>303.6</b>	+52.7	+ 21.0%
Operating Profit	52.4	<b>66.2</b>	+13.6	+ 26.1%
Ordinary Profit	76.8	<b>84.9</b>	+8.0	+ 10.5%
Profit Attributable to Owners of Parent	53.4	<b>60.9</b>	+7.4	+ 13.9%

## ■ Estimated impacts of foreign exchange

### ◆ Foreign exchange gains and losses (non-operating income and expenses)

FY2023/3 results: forex gain of +¥1.51B (¥11.13 weaker against US\$)

FY2024/3 forecast: forex gain of +¥0.28B (¥11.45 weaker against US\$)

### ◆ New foreign exchange rate assumption for FY2024/3: ¥144.99/US\$ (initial assumption at : ¥133.54/US\$)

### <Assumed Foreign Exchange Sensitivity>

Estimated impacts of ¥1 weaker against US\$ from Q2 FY2024/3 and onwards are as below:

Revenue: ¥51M

Operating profit: ¥20M

Non-operating profit: ¥22M

(Because loans to an US subsidiary have been converted to shares, the impacts of foreign exchange fluctuations will be reduced YoY).

# Business Topics:

## I. CRO (Nonclinical) Business

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Hideshi Tsusaki, DVM, PhD  
Managing Director of the Board,  
President of Nonclinical Business and Global BD

# CRO Business: Contracts in Nonclinical Business (in JPY)



(Units: JPY100M)



**1Q YOY+¥1.19B**  
 SNBL: -¥0.17B  
 Domestic: +¥1.35B  
 Overseas: -¥1.52B

INA: +¥1.36B  
 Domestic: +¥0.99B  
 Overseas: +¥0.37B

Exchange rate  
 (average for the period)  
 ¥139.63/USD

**Note:**

- Excluding Ina Research through FY2022 Q1
- Overseas contracts are converted to yen using the exchange rate at the end of each period
- Cancelled contracted projects are recorded as a negative figure at the time of cancellation

Backlog at year-end  
 Overseas contracts ratio

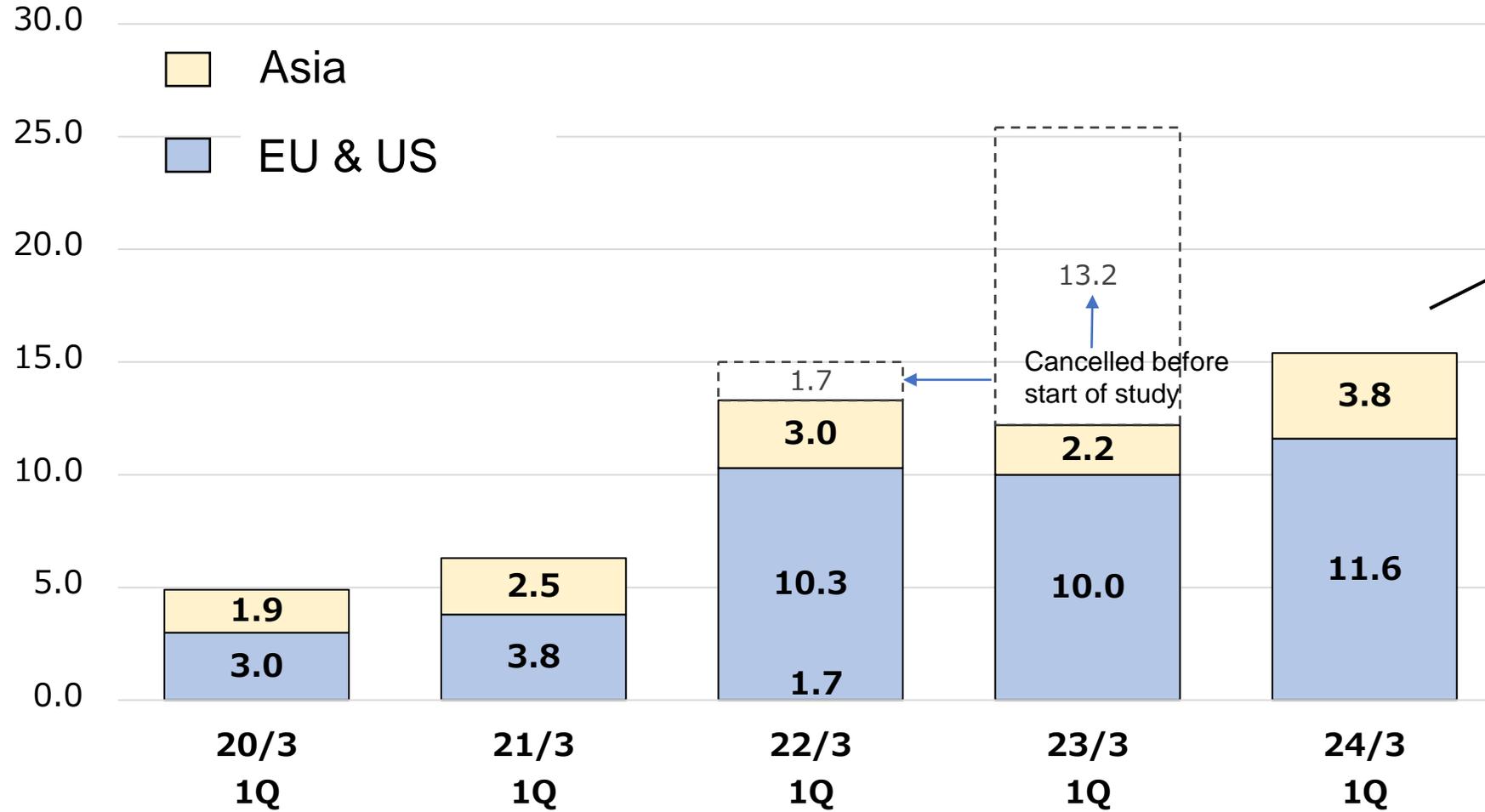
¥12.15B	¥12.53B	¥17.22B	¥25.76B	¥33.34B
15.0%	17.6%	26.4%	46.2%	26.0%

**1Q YOY+¥7.59B**  
 SNBL: +¥1.86B  
 INA: +¥5.73B

# CRO Business: Overseas Contracts in Nonclinical Business



(Units:\$M)



**1Q YOY -\$10.0M**  
 SNBL: -\$12.7M  
 EU & US: -\$10.1M  
 Asia: -\$2.6M

INA: +\$2.7M  
 EU & US: ±\$0.0M  
 Asia: +\$2.7M

- Note:**
- Excluding Ina Research through FY2022 Q1
  - Cancelled contracted projects are recorded as a negative figure at the time of cancellation

Backlog at year-end

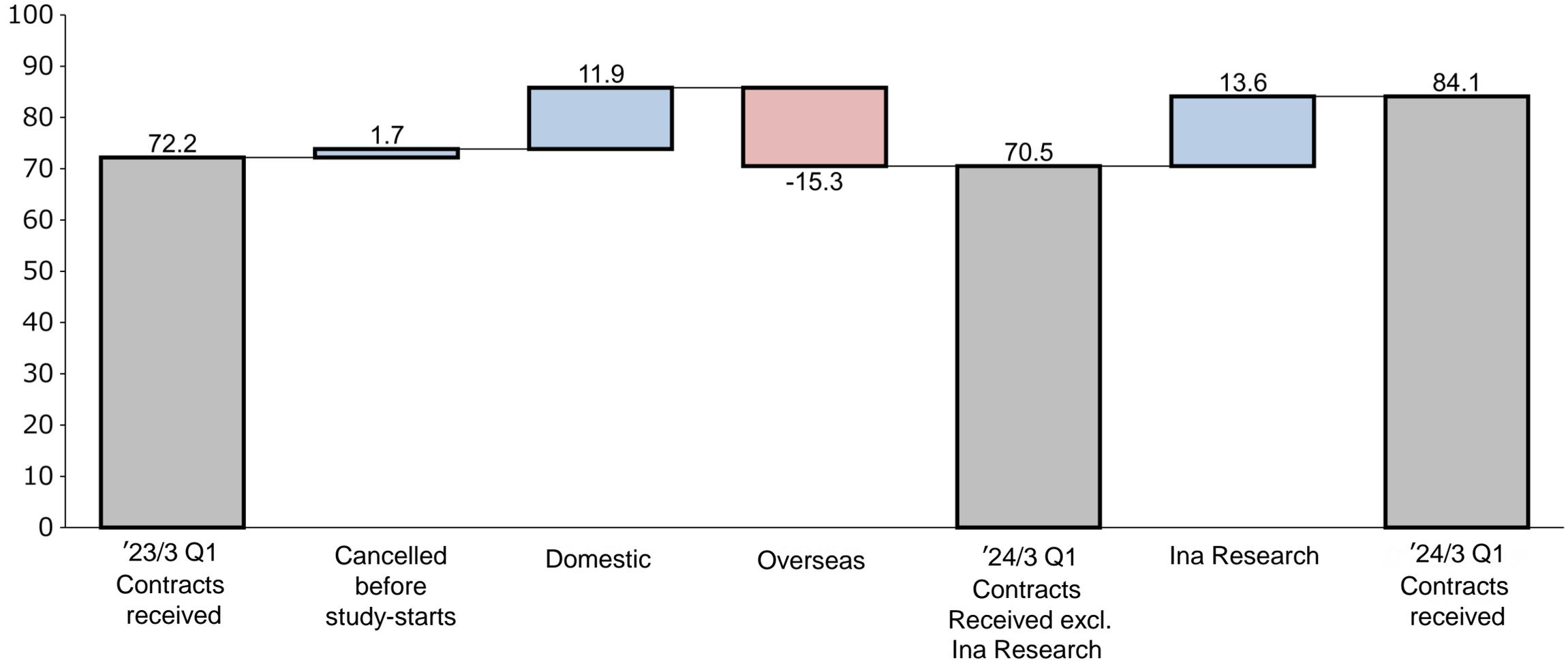
\$21.7M	\$22.0M	\$47.1M	\$86.4M	\$100.7M
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**1Q YOY+\$14.3M**  
 SNBL: -\$11.1M  
 INA: +\$25.4M

# CRO Business: YOY Analysis of Contracts in FY2023 Q1

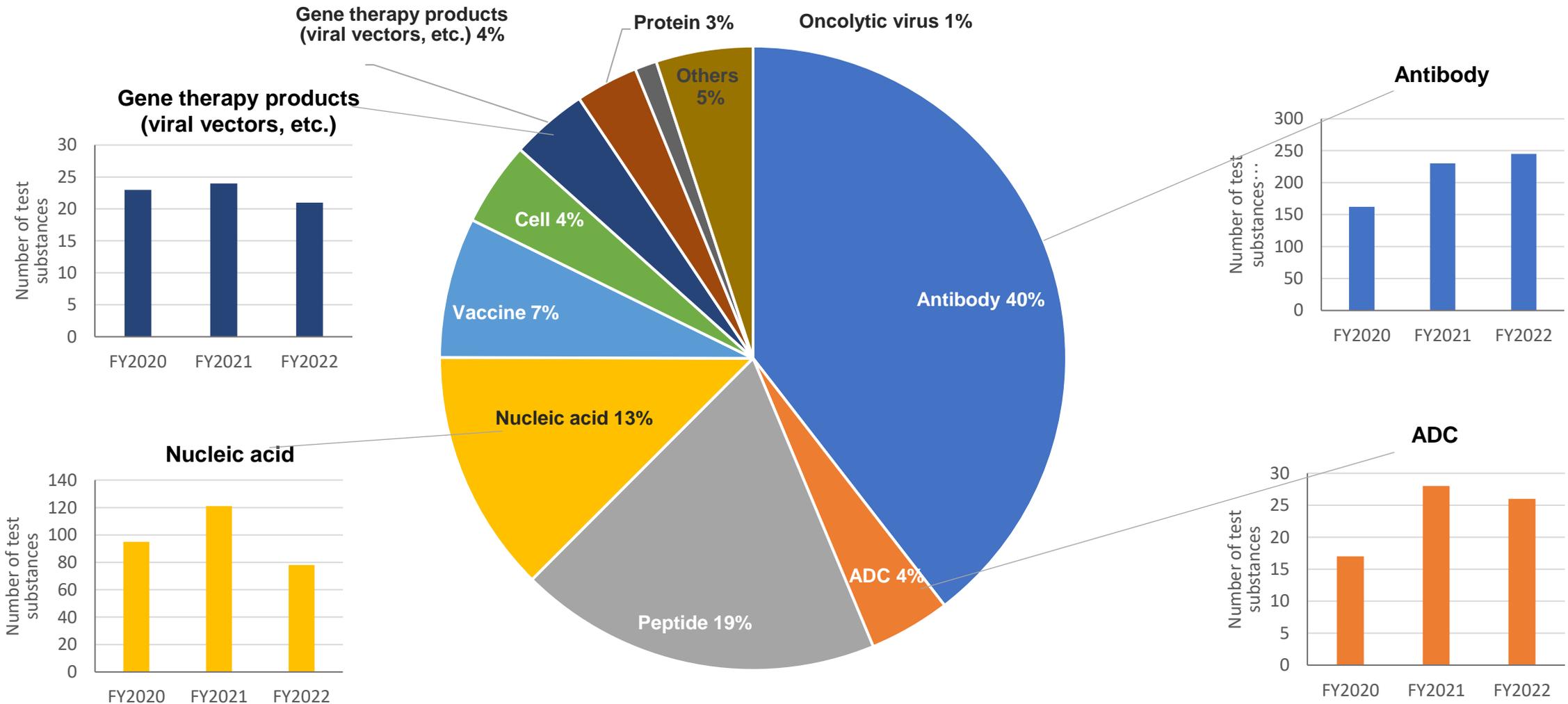


(Units: JPY100M)



Cancellation prior to contracted study start decreased over the previous year  
 (FY2022 Q1: ¥0.54B -> FY2023 Q1: ¥0.37B)

# CRO Business: Contracts by Drug Discovery Modality



Contracts other than small molecule drugs for FY2023 Q1  
(Number of test substances) 616 compounds

## **Preferred Contracts**

- The number of preferred contracts with domestic pharmaceutical companies, which were concluded in FY2022, is growing and progressing as expected.

## **Signed comprehensive contract research agreements at the drug discovery stage**

- In addition to the drug discovery phase research contracted with Astellas Pharma Inc. that has been ongoing since 2019 (and previously made public), similar contracts with other several domestic pharmaceutical companies have newly initiated as scheduled.

## **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**

- Operational due diligence for preferred contracts with several major overseas pharmaceutical companies is in full swing.

## **Synergy with Ina Research**

- Ina Research, a subsidiary of SNBL from 2022, received a large package of studies necessary for agrichemical sales application from a domestic manufacture for the first time as part of the SNBL Group.

# Business Topics:

## II. Acquisition of Satsuma Pharmaceuticals

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Ken Takanashi, MBA, CPA  
Executive Vice President

# TR Business: Progress on SNBL's Nasal Delivery Technology

## For Systemic Absorption

**Satsuma**

For relief acute migraine



Filed the NDA to the US FDA in Mar. 2023, the PDUFA date is set on Jan 17, 2024.

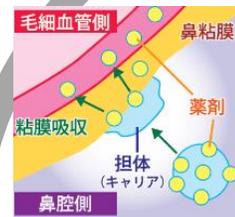
**SNLD**

For improvement the wearing-off in Parkinson disease



Completed the clinical P1 study in Jan. 2023, and preparing next clinical studies.

## SNBL's Proprietary Nasal Drug Delivery System



### Nasal Drug Carrier

- ✓ Muco-adhesive powder carrier
- ✓ Specific optimizations for each API characteristic

### Nasal Delivery Device

- ✓ User-friendly
- ✓ Light-weight/compact
- ✓ Consistent delivery
- ✓ Specific design for each nasal application



## For Vaccination to Enable Blocking Immunity

- Promotion of nasal vaccine research by the R&D center for nasal mucosal vaccines which has been newly established

## For Nose-to-Brain Delivery

- Preparing evaluations of the special device intended for clinical uses
- Published the research article on the nose-to-brain delivery of poorly BB permeable drug in NHPs in Journal of Controlled Release, an authoritative scientific paper in fields of drug delivery systems

Business alliance with Shionogi Pharma, co., Ltd., a Contract Development and Manufacturing Organization

# TR Business: Acquisition of Satsuma Pharmaceuticals

## June 8, 2023: Wholly Owned Satsuma's Share

### 【Sequence】

**JUN 2016~:** Established in the U.S. by licensing out our intranasal administration technology. Raised funds mainly from U.S. institutional investors and listed on Nasdaq.

**NOV 2022:** Release of clinical trial data from Phase 3 drug efficacy study (SUMMIT)

*Satsuma stopped building its own sales network, which would require additional funding, and strived to reduce operating costs. Meanwhile, Satsuma has shifted to a policy of maximizing shareholder value through seeking commercial partners and strategic business partners, and continuing development for approval. This is because STS101 can be approved by the FDA without further clinical trials and its commercial potential remains large and is not significantly compromised by the results of the SUMMIT trial.*



Specialty Pharma  
for Nasal Migraine Drug



**MAR 2023:** Apply for the NDA

**APR 2023:** Execution of the Merger Agreement

**MAY 2023:** Tender Offer begins in the U.S. market

**JUN 2023:** SNBL owns 100% share

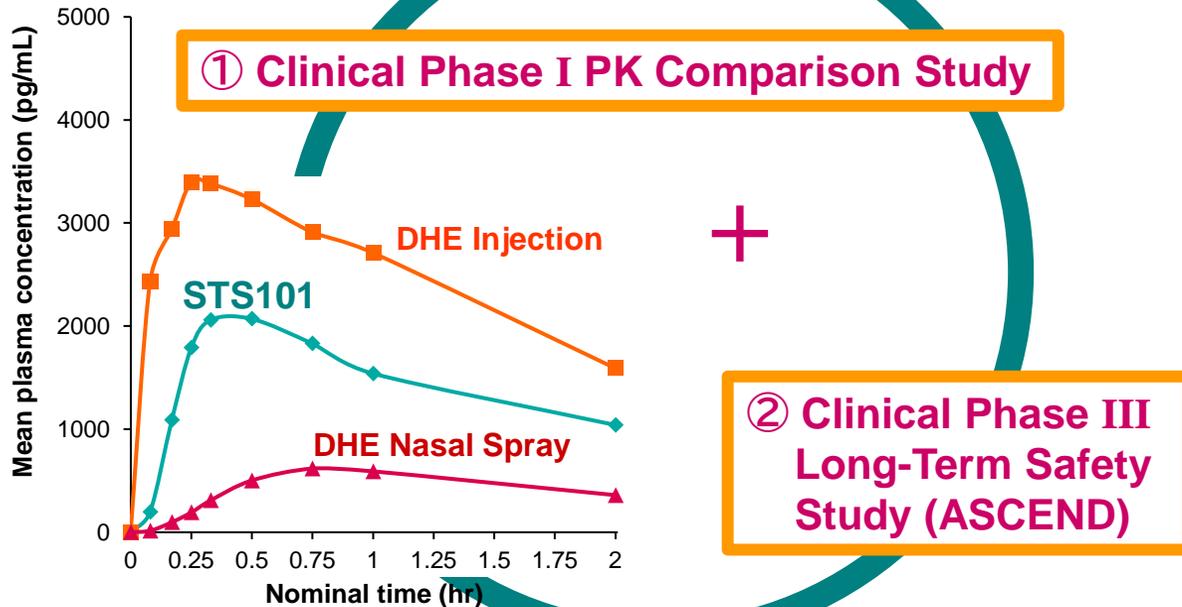


### 【Development Schedule of STS101】



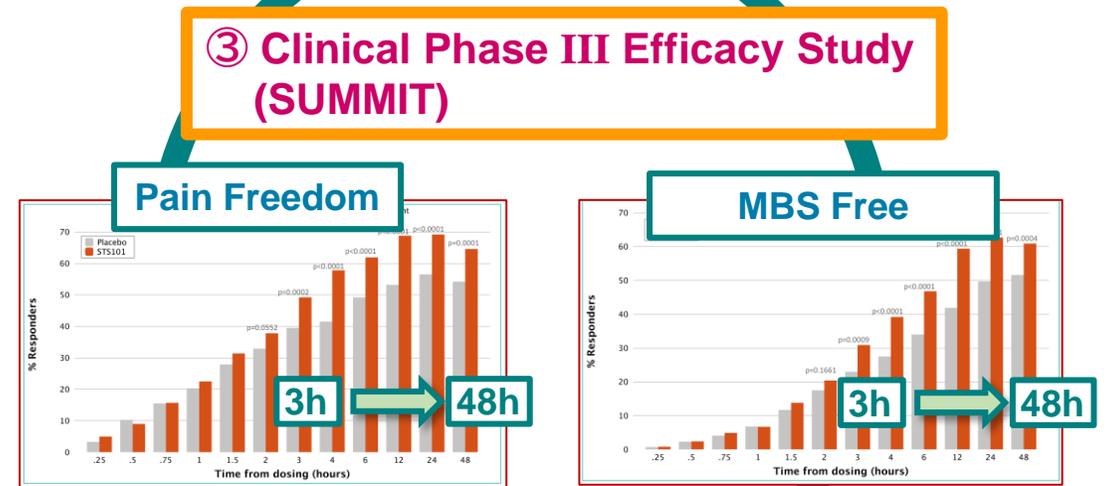
## Clinical Study Data Used for the NDA File

Filed the NDA using the data based on the following two clinical studies which are possibly available for the NDA approval through the discussions with the FDA.



## Clinical Study Data To be Possibly Incorporated in The Label

Planned to negotiate to incorporate the efficacy data based on the following clinical study with the FDA, in order to differentiate from the existing DHE products.

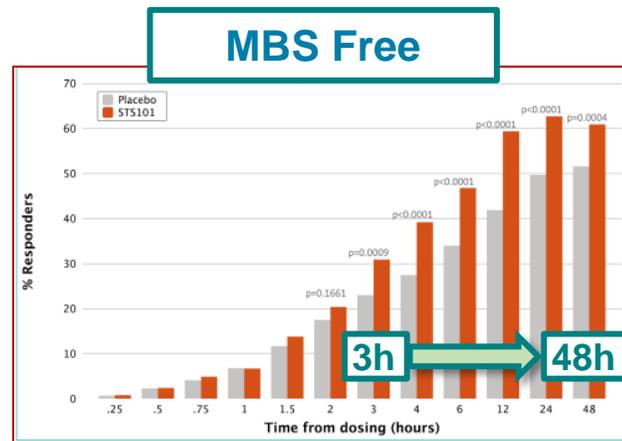
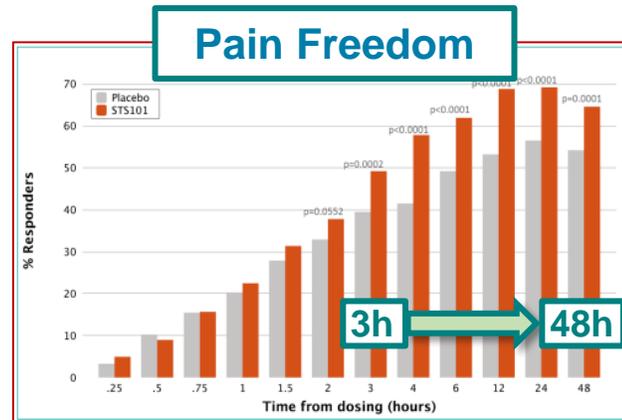


## Features of STS101

① There is a certain percentage of acute migraine nonresponders for Triptans and Gepants<sup>\*1, 2</sup>. STS101 has dihydroergotamine, an active agent, which is possibly effective to the non-responders<sup>\*2</sup>.

② It is reported that 55% of patients preferred a long-acting agent versus a rapid-onset, short-acting<sup>\*3</sup>.

In STS101 SUMMIT Study, a clinical Phase 3 efficacy study, STS101 showed superior differences versus placebo on freedom from pain and MBS (most bothersome symptom) at 3 to 48 hours post-administration, although failed to meet the co-primary endpoints (see the right figures).



Satsuma's Market Research Survey to High-Prescribers of Migraine Drugs (n=100)

Irrespective what efficacy information of the SUMMIT trial was included in STS101, respondents indicated intent to prescribe STS101 to ~30% of their migraine patients

\*1: Dodick, Headache, 2005, 45(2): 156-162.

\*2: Silberstein, Headache, 2020, 60: 40-57.

\*3: Malik, et. al, Headache, 2006, 46: 773-780.

\*4: Winner, et. al., Arch Neurology, 1996, 53(2): 180-184.

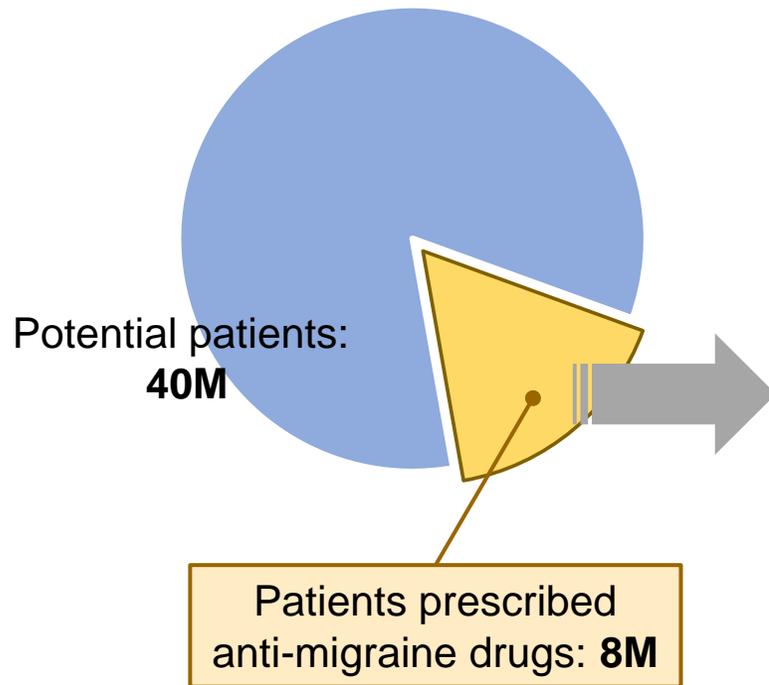
\*5: Lipton, et. al., Lancet Neurology, 2023, 22: 209-217.

\*6: Presentation Material of SUMMIT Phase 3 Efficacy Trial Topline Results, Satsuma Pharmaceutical, Inc., Nov. 14, 2022.

# TR Business: Market Targeted by STS101

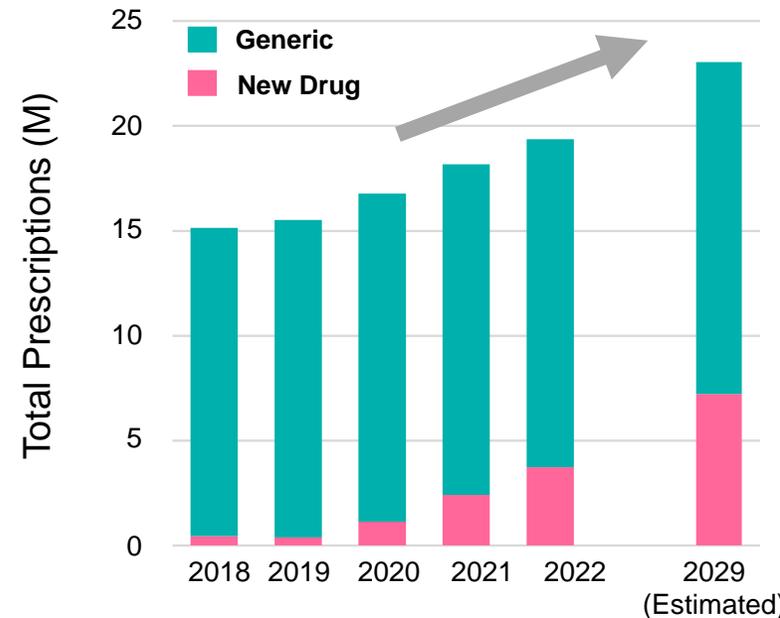
## US Potential Migraine Patients

Numerous Patients



## US Prescriptions of Anti-Migraine Drugs

Increasing Market based on New Drugs



Market for new drugs is a target of STS101

Expected peak share of STS101 is more than 5% of the market based on new drugs.

Expected peak sales of STS101: A few hundred million dollars per year

“High-Prescribers of Migraine Drugs indicated intent to prescribe STS101 to ~30% of their migraine patients.”

Source: Acute Migraine Market: IQVIA USC 20700 Anti-migraine not including preventive mAbs or atogepant



## Financial Data

(In millions of yen)	2018/3	2019/3	2020/3	2021/3	2022/3	2023/3	2024/3 Forecasts
Revenue	16,600	15,658	14,561	15,110	17,748	25,090	30,368
YoY(%)	-3.7%	-5.7%	-7.0%	3.8%	17.5%	41.4%	21.0%
Gross profit	5,204	6,177	7,615	7,554	9,687	13,046	16,278
Ratio of gross profit to revenue (%)	31.3%	39.5%	52.3%	50.0%	54.6%	52.0%	53.6%
Operating profit	-697	829	2,228	2,529	4,195	5,245	5,020
YoY(%)	-	-	168.5%	13.5%	65.9%	25.0%	-4.3%
Share of profit of entities accounted for using equity method	637	361	888	846	1,439	2,489	
Ordinary profit	-813	1,613	3,121	3,645	7,078	9,194	7,180
Profit before income taxes	-1,507	1,650	3,062	4,175	8,183	7,759	
Income taxes	2,013	-308	414	497	1,016	1,708	
Profit attributable to owners of parent	-3,555	1,950	2,550	3,661	7,127	6,060	4,780
Profit per share (yen)	-85.41	46.84	61.25	87.95	171.20	145.56	114.81
Overseas sales	4,868	4,015	2,317	2,100	3,091	6,575	
Overseas sales ratio	29.3%	25.6%	15.9%	13.9%	17.4%	26.2%	
Revenue from international sponsors	7,982	9,958	12,386	15,840	22,181	25,751	
Net assets	26,215	28,477	16,381	15,838	19,723	26,359	
Total assets	57,493	54,329	39,002	36,972	39,312	57,242	
Interest-bearing debt	19,139	16,158	15,123	12,864	9,281	18,931	
Equity ratio (%)	45.5%	52.3%	41.8%	42.6%	49.8%	45.8%	
Capital expenditures	1,274	1,612	1,514	1,025	1,703	5,663	6,875
Depreciation	1,472	1,361	1,229	1,187	1,177	1,544	1,800
R&D expenses	518	339	400	392	425	683	928
Ratio of R&D expenses to revenue (%)	3.12%	2.17%	2.75%	2.59%	2.39%	2.72%	3.06%
Number of employees at the end of the fiscal year	1,385	935	985	986	994	1,208	1,382
ROE (%)	-14.6%	7.1%	11.4%	22.9%	40.4%	26.5%	
ROA (%)	-1.4%	2.9%	6.7%	9.6%	18.6%	19.0%	
ROIC (%)	—	—	11.7%	12.3%	18.4%	17.9%	
Ratio of operating profit to revenue (%)	-4.2%	5.3%	15.3%	16.7%	23.6%	20.9%	16.5%
Ratio of ordinary profit to revenue (%)	-4.9%	10.3%	21.4%	24.1%	39.9%	36.6%	23.6%
Cash dividends per share (yen)	-	3.0	5.0	20.0	40.0	50.0	50.0
Dividend payout ratio (%)	-	6.4%	8.2%	22.7%	23.4%	34.3%	46.2%

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 First Three Month of Fiscal Year Ending 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>



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