

Third Quarter of Fiscal Year Ending March 31, 2024 Consolidated Financial Results Briefing

Presentation Material

February 2, 2024



SHIN NIPPON BIOMEDICAL LABORATORIES, LTD.

1. Q3 FY2024/3 Overview & Future Outlook



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

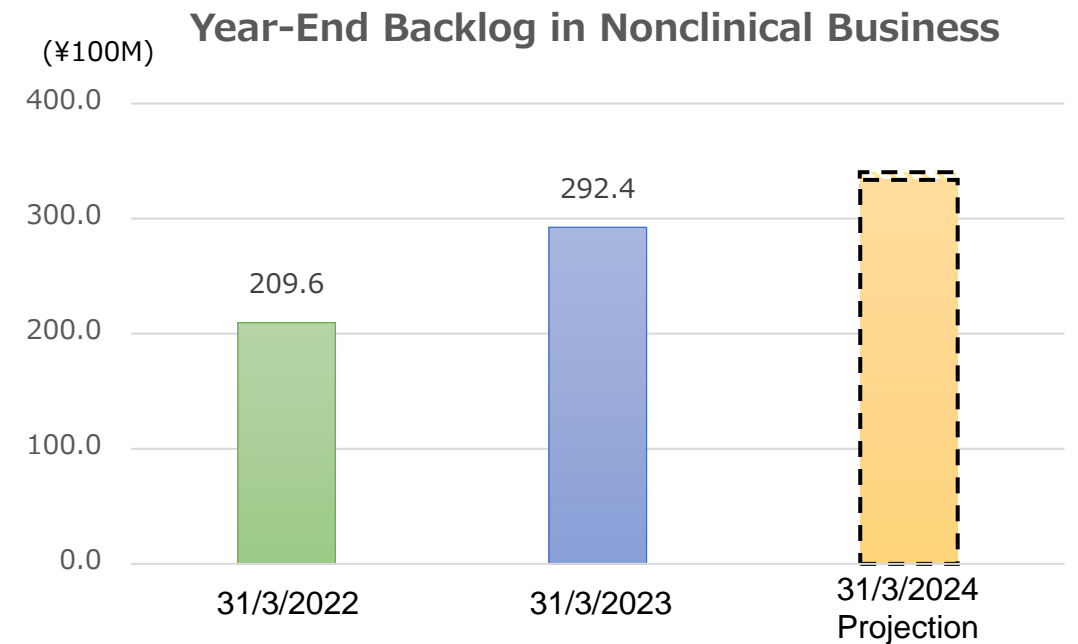
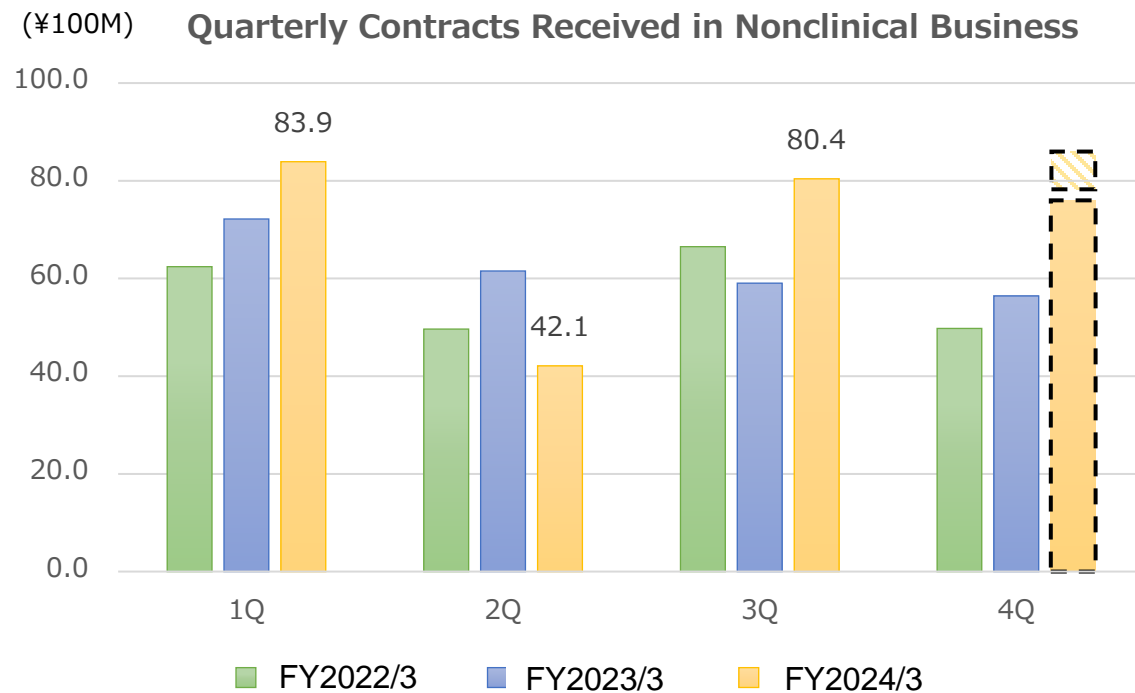
1. Q3 FY2024/3 Financial Results and Revision on Full-year Forecasts

- Full-year forecasts for revenue and profits revised downwardly due mainly to weaker-than-planned revenue in nonclinical CRO business. Considering the year-to-date contracts received in Q3, we foresee that contracts received to be posted as revenue in the current financial year will be lower than projected.
- However, situation of nonclinical CRO business has been improving and in recovery: record-high contracts received posted in Q3 and we expect it to record another record-high in Q4.
- Record-high equity method investment gain of ¥2.01B from PPD-SNBL which undertakes the clinical CRO business, also achieved in Q3.

2. Satsuma's intranasal migraine drug candidate STS101

- Satsuma Pharmaceuticals received Complete Response Letter (CRL) for STS101 NDA from FDA on 17 Jan 2024 (US time).
- FDA's CRL indicated no concern on clinical data and Satsuma will consider a re-submission for the NDA of STS101 based on results of a meeting with FDA that will be scheduled in the near future.

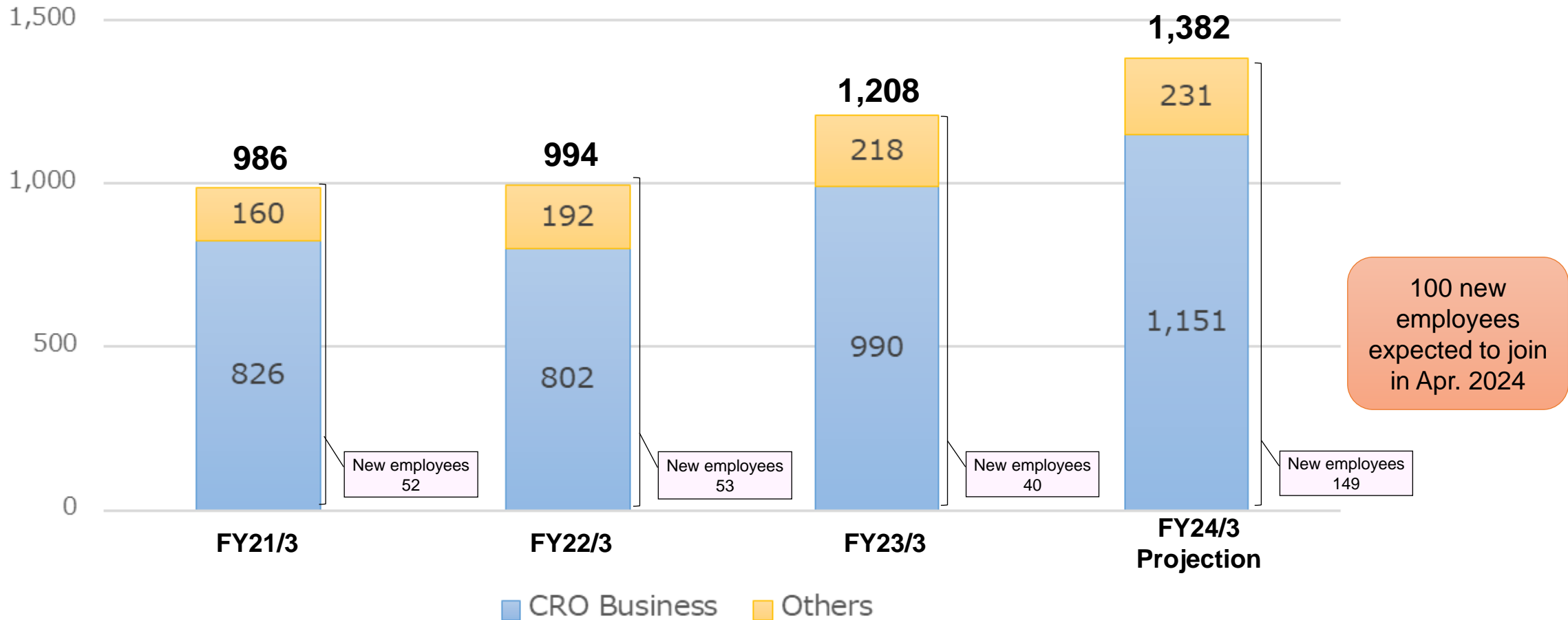
Contracts Received and Backlog in Nonclinical Business



Number of Employees

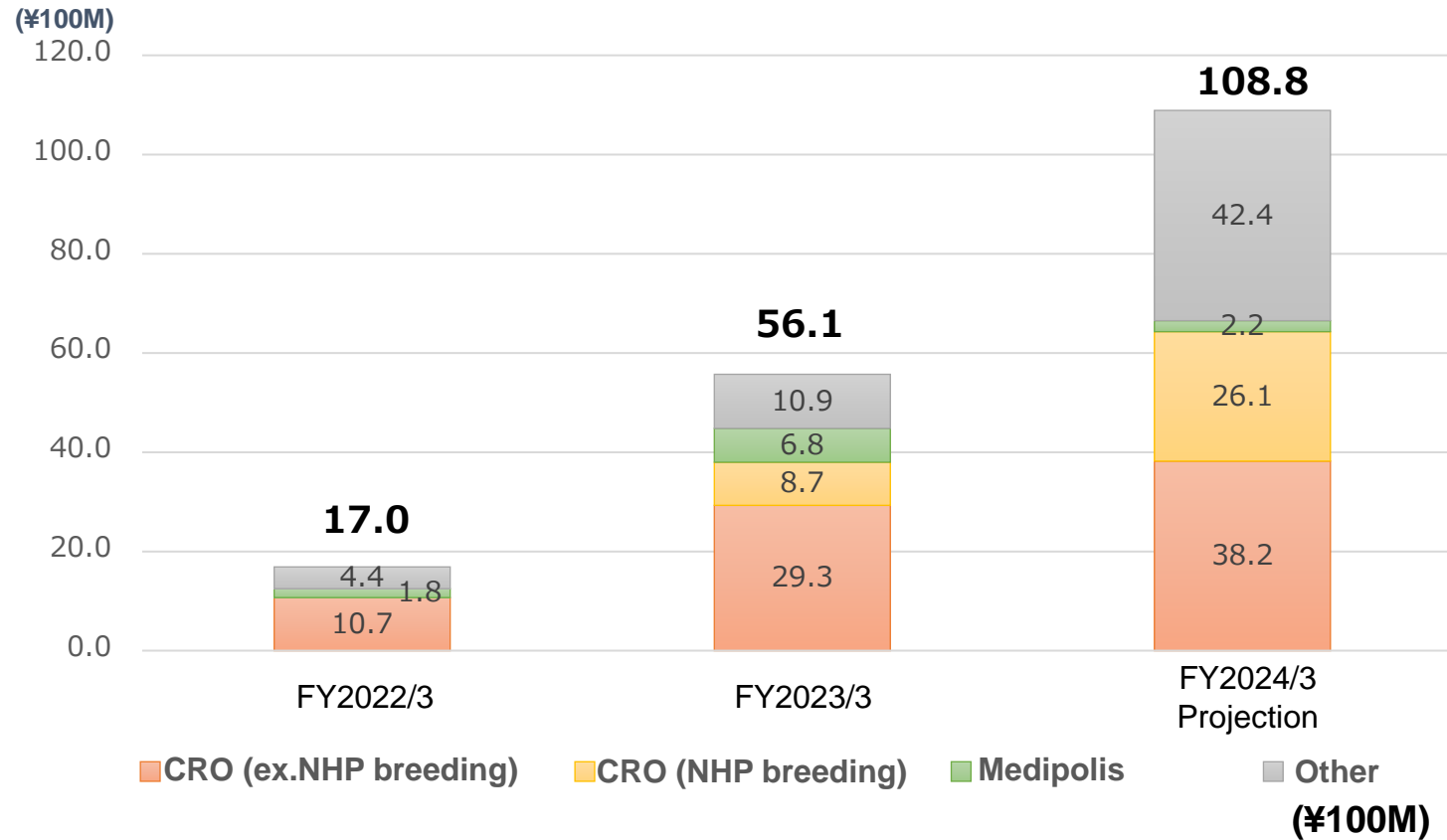


Number of Employees



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

CAPEX



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

	FY2022/3	FY2023/3	FY2024/3	
			Forecast (Revised)	Yoy
CAPEX	17.0	56.1	108.8	+52.7
Depreciation	11.7	15.4	19.8	+4.4

Business Overview



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)

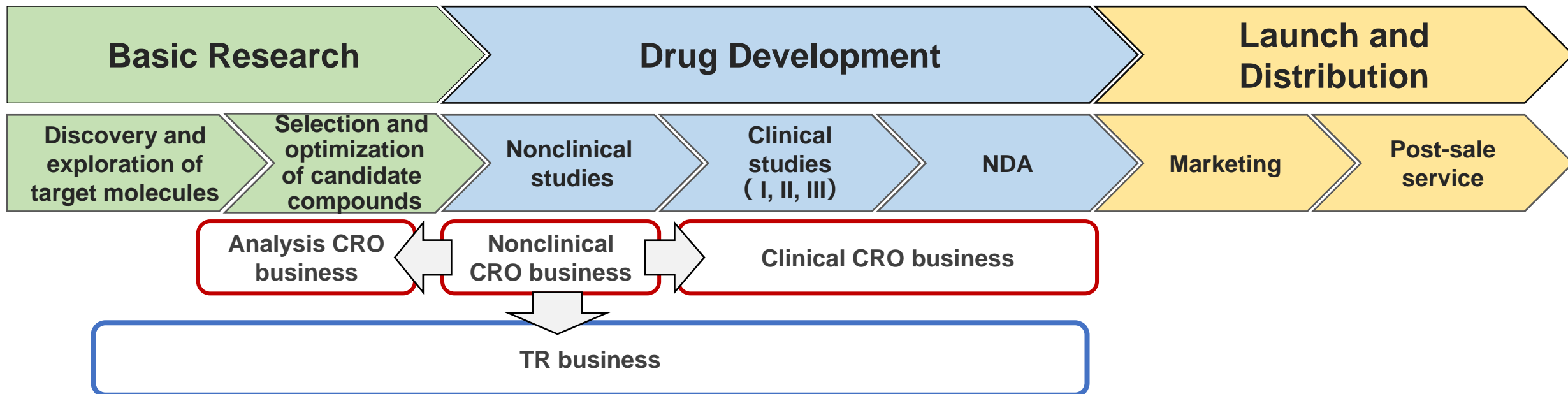
Foundation: September 16, 1957 (Incorporation: May 1973)

HQ location: Kagoshima City, Kagoshima Pref.

Main business: Contract Research Organization (CRO) business

Number of employees: 1,344 Female ratio: 51.1% (as of 31/12/2023)

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



Outline of Q3 FY2024/3 Consolidated Financial Results

Q3 FY2024/3 Consolidated Financial Results Highlights



Operating profit decreased due mainly to three factors: increased labor costs, increased SG&A led by rising prices of study materials and expenses for breeding animals, and impacts of recently-consolidated subsidiary Satsuma (¥0.81B). Ordinary profit decreased due mainly to a less contribution of foreign currency gain which decreased by ¥0.91B compared to the same period of previous year. Equity method investment gain from PPD-SNBL was record-high ¥2.01B for Q3 and contributed to increase the ordinary profit by ¥0.40B YoY.

(¥100M)

	Q3 FY2023/3 Results	FY2024/3		
		Cumulative Q3 Results	YoY changes	
Revenue	163.7	179.8	+16.1	+ 9.9%
Operating Profit	37.8	25.3	-12.5	-33.0%
Ordinary Profit	68.8	48.8	-20.0	-29.0%
Ordinary Profit (excl. FX impact)	56.9	46.0	-10.9	-19.1%
Profit Attributable to Owners of Parent	43.5	37.9	-5.6	-12.8%

←Record-high for Q3.

←Consolidation of Satsuma from Q3 resulting in increase of SG&A by ¥0.81B

←FX gain decreased by ¥0.91B YoY. Share of profit of equity method affiliate PPD-SNBL increased by ¥0.40B YoY.

Q3 FY2024/3 Financial Results by Segment



Cumulative Q3 Revenue and Operating Profit/Loss by Segment (¥1M)

		Q3 FY2022/3	Q3 FY2023/3	Q3 FY2024/3	Increase
CRO Business	Revenue	12,406	15,515	17,483	12.7%
	Operating Profit	3,854	4,453	4,342	-2.5%
	OP Ratio	31.1%	28.7%	24.8%	
	Equity Method Profit	848	1,984	2,148	8.3%
	(of which, PPD-SNBL)	864	1,611	2,011	24.8%
	Business Profit	4,702	6,437	6,490	0.8%
	BP Ratio	37.9%	41.5%	37.1%	
TR Business	Revenue	12	12	9	
	Operating Profit	-496	-518	-1,627	
Medipolis Business	Revenue	414	492	492	
	Operating Profit	11	-167	-100	
Other	Revenue	569	1,165	1,163	
	Operating Profit	-17	115	95	
Adjustments	Revenue	-456	-814	-1,165	
	Operating Profit	-50	-99	-173	
Total	Revenue	12,946	16,371	17,984	9.9%
	Operating Profit	3,300	3,783	2,535	-33.0%
	OP Ratio	25.5%	23.1%	14.1%	

←A record high Business Profit in CRO Business posted in cumulative Q3.

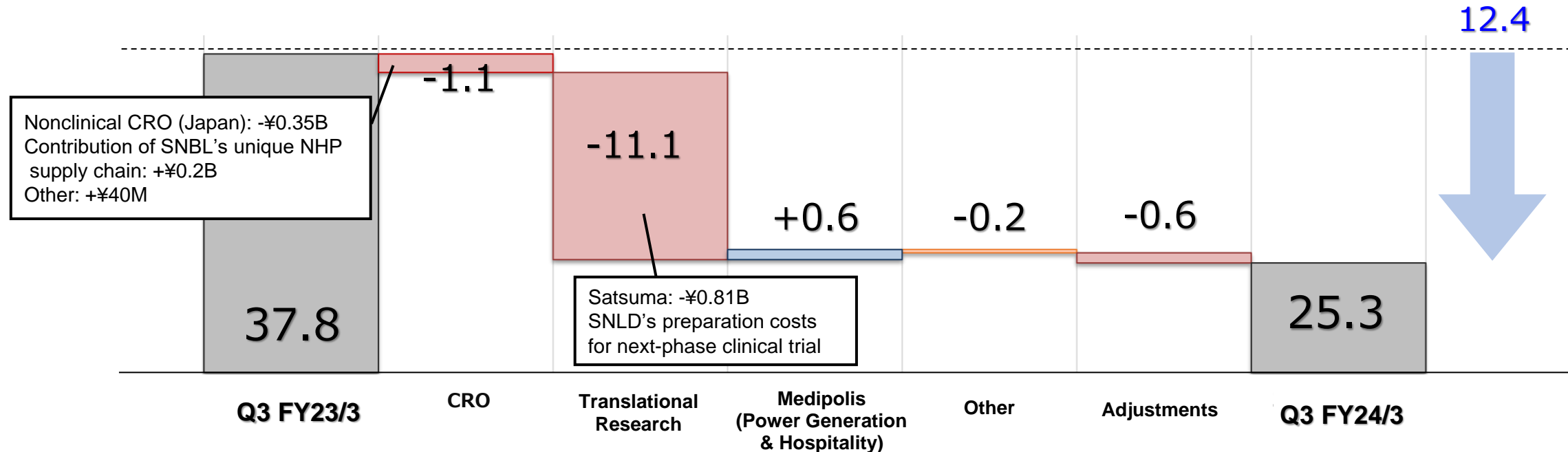
←Satsuma's ¥0.81B is a main factor for OP decline.

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

PPD-SNBL in clinical business (equity stake: 40%) and (former SNBL China. Current equity stake: 49.9%) are JVs and SNBL's equity method affiliates. Their contribution to SNBL's consolidated earnings is recorded as "share of profit of entities accounted for using equity method" under non-operating income.

YoY Comparison of Consolidated Operating P/L: Q3 FY2024/3

						(¥100M)
	CRO Business	Translational Research Business	Medipolis Business (Power Generation & Hospitality)	Other	Adjustments	Operating Profit Total
Q3 FY2024/3 Results	43.4	-16.2	-1.0	0.9	-1.8	25.3
Q3 FY2023/3 Results	44.5	-5.1	-1.6	1.1	-1.1	37.8
YoY changes	-1.1	-11.1	+0.6	-0.2	-0.6	-12.4

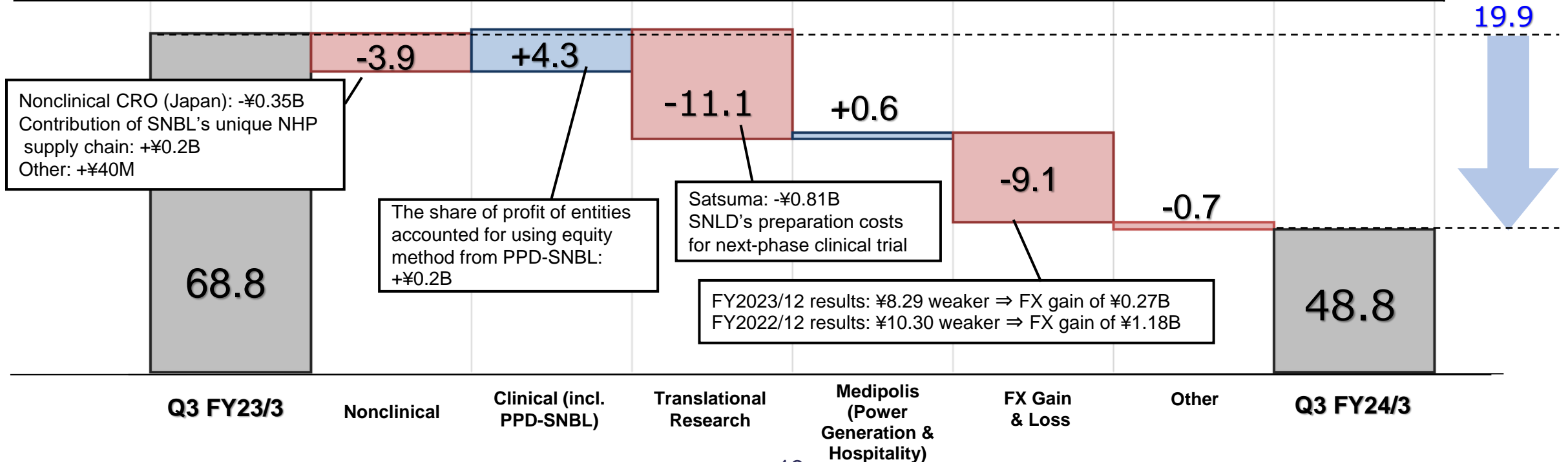


YoY Comparison of Consolidated Ordinary P/L: Q3 FY2024/3



(¥100M)

	CRO Business		Translational Research Business	Medipolis Business (Power Generation & Hospitality)	Foreign Exchange Gain & Loss	Other	Ordinary Profit Total
	Nonclinical	Clinical (incl. PPD-SNBL)					
Q3 FY2024/3 Results	44.9	21.4	-16.2	-1.0	2.7	-3.0	48.8
Q3 FY2023/3 Results	48.8	17.1	-5.1	-1.6	11.8	-2.2	68.8
YoY changes	-3.9	+4.3	-11.1	+0.6	-9.1	-0.7	-19.9



Financial Forecast Revision for FY2024/3

Financial Forecast Revision for Full-year FY2024/3



Revenue is expected to undershoot the forecast announced on Aug 2, 2023, due mainly to transiently declined contracts received in nonclinical CRO business in Q2, which will result in a decrease of full-year contracts received and revenue to be recorded during the current financial year. Operating profit is revised downwardly as we foresee lower-than-expected revenue will not be able to fully absorb the increased costs related to strategic initiatives involving a significant rise in labor costs, as well as rising prices for study materials, etc. The decrease in ordinary profit, however, will be limited thanks to stronger-than-expected contribution of PPD-SNBL, an equity method affiliate in clinical CRO business.

(Units: ¥100M)

	FY2024/3			
	Forecast (Aug 2, 2023)	New Forecast (Feb 2, 2024)	Changes against original forecast	
Revenue	303.6	261.9	-41.7	-13.8%
Operating Profit	50.2	34.7	-15.5	-30.9%
Ordinary Profit	71.8	63.9	-7.9	-11.0%
Profit Attributable to Owners of Parent	47.8	39.7	-8.0	-16.8%

Business Performance by Segment



Revenue and Operating Profit/Loss by Segment

(¥1M)

		FY2021/3	FY2022/3	FY2023/3	FY2024/3 (projection)	Increase
CRO Business	Revenue	14,508	17,047	24,000	25,835	7.6%
	Operating Profit	3,393	5,035	6,336	6,833	7.8%
	OP Ratio	23.4%	29.5%	26.4%	26.4%	
	Equity Method Profit	848	1,438	2,489	2,698	8.4%
	(of which, PPD-SNBL)	864	1,258	1,967	2,579	31.1%
	Business Profit	4,241	6,473	8,825	9,531	8.0%
	BP Ratio	29.2%	38.0%	36.8%	36.9%	
TR Business	Revenue	12	12	16	15	
	Operating Profit	-708	-746	-879	-2,614	
Medipolis Business	Revenue	552	563	683	595	
	Operating Profit	-54	-17	-203	-241	
Other	Revenue	503	968	1,437	1,378	
	Operating Profit	-35	41	110	76	
Adjustments	Revenue	-466	-844	-1,047	-1,633	
	Operating Profit	-65	-116	-118	-584	
Total	Revenue	15,110	17,748	25,090	26,190	4.4%
	Operating Profit	2,529	4,195	5,245	3,470	-33.8%
	OP Ratio	16.7%	23.6%	20.9%	13.2%	

←A record high Business Profit in CRO Business posted in cumulative Q3.

←Satsuma's ¥1.41B is a main factor for OP decline.

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

PPD-SNBL in clinical business (equity stake: 40%) and (former SNBL China. Current equity stake: 49.9%) are JVs and SNBL's equity method affiliates. Their contribution to SNBL's consolidated earnings is recorded as "share of profit of entities accounted for using equity method" under non-operating income.

Contracts Received and Backlog in Nonclinical Business



Quarterly Contracts Received in Nonclinical Business

(¥1M)

	FY2022/3					FY2023/3					FY2024/3			
	Q1	Q2	Q3	Q4	Full Year	Q1	Q2	Q3	Q4	Full Year	Q1	Q2	Q3	Q3 Cumulative
Contracts Received	6,242	4,965	6,652	4,979	22,839	7,219	6,153	5,905	5,642	24,920	8,398	4,217	8,044	20,659
Japan	4,593	3,854	4,232	3,638	16,318	3,887	3,754	3,726	4,971	16,339	6,208	3,471	5,051	14,730
Overseas	1,649	1,111	2,420	1,341	6,521	3,332	2,399	2,179	671	8,581	2,189	745	2,993	5,928
US&Europe	1,311	827	1,759	802	4,699	2,844	484	1,489	420	5,237	1,661	827	1,830	4,319
Asia	338	283	662	539	1,822	488	1,915	690	251	3,344	527	-81	1,162	1,608
Overseas Ratio	26.4%	22.4%	36.4%	26.9%	28.6%	46.2%	39.0%	36.9%	11.9%	34.4%	26.1%	17.7%	37.2%	28.7%
Backlog	17,216	17,671	19,960	20,966	20,966	25,756	33,672	32,585	29,248	29,248	33,329	32,210	33,863	33,863

*Contracts received: net amounts of contracts received excluding cancellations that occurred during the period.

Financial Forecast Revision for Full-year FY2024/3



Ordinary profit for the full year ending March 31, 2024, is expected to be almost flat (-2.0% YoY), if impacts by a consolidation of Satsuma (-¥1.41B) and FX valuation profit/loss (-¥1.24B) are excluded.

(Units: ¥100M)

	FY2023/3	FY2024/3		
		Forecast (Feb 2, 2024)	YoY changes	
Revenue	250.9	261.9	+11.0	+4.4%
Operating Profit	52.4	34.7	-17.7	-33.8%
Ordinary Profit	91.9	63.9	-28.0	-30.5%
Profit Attributable to Owners of Parent	60.6	39.7	-20.9	-34.4%

Business Profit excl. consolidation of Satsuma, FX impacts, and extraordinary gain/loss			
FY2023/3*	FY2024/3*		
	Forecast (Feb 2, 2024)	YoY changes	
250.9	261.9	+11.0	+4.4%
52.4	48.9	-3.5	-6.7%
76.8	75.3	-1.5	-2.0%
53.4	51.2	-2.2	-4.1%

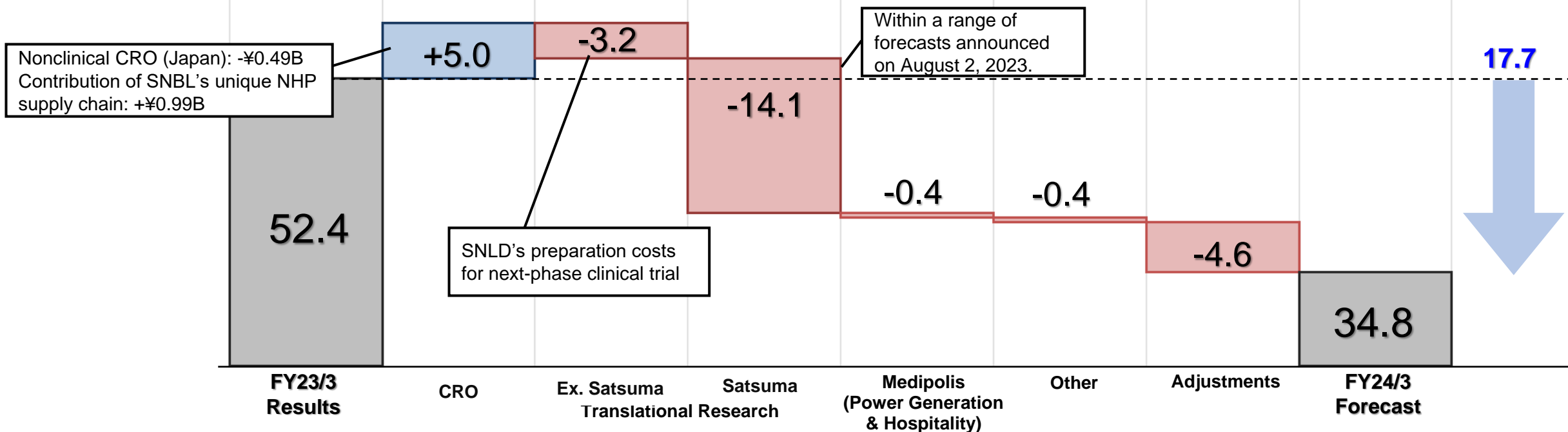
* Excluding impacts by a consolidation of Satsuma, FX valuation profit/loss of loans to subsidiaries, etc., and extraordinary gain/loss.

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



(Units: ¥100M)

	CRO Business	Translational Research Business		Medipolis Business (Power Generation & Hospitality)	Other	Adjustments	Operating Profit Total
		Ex. Satsuma	Satsuma				
FY2024/3 Forecast	68.3	-11.9	-14.1	-2.4	0.7	-5.8	34.8
FY2023/3 Results	63.3	-8.7	0.0	-2.0	1.1	-1.3	52.4
YoY changes	+5.0	-3.2	-14.1	-0.4	-0.4	-4.6	-17.7

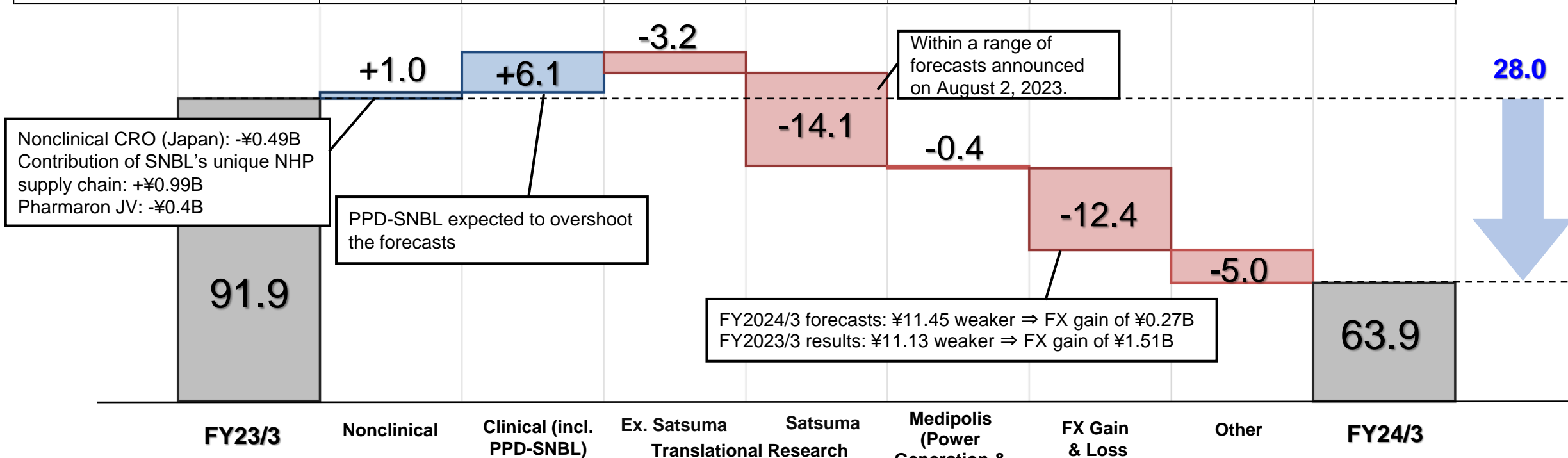


YoY Comparison of Consolidated Ordinary P/L: FY2024/3



(¥100M)

	CRO Business		Translational Research Business		Medipolis Business (Power Generation & Hospitality)	Foreign Exchange Gain & Loss	Other	Ordinary Profit Total
	Nonclinical	Clinical (incl. PPD-SNBL)	Ex. Satsuma	Satsuma				
FY2024/3 Forecast	69.8	27.2	-11.9	-14.1	-2.4	2.7	-7.4	63.9
FY2023/3 Results	68.8	21.1	-8.7	0.0	-2.0	15.1	-2.4	91.9
YoY changes	+1.0	+6.1	-3.2	-14.1	-0.4	-12.4	-5.0	-28.0



■ Estimated impacts of foreign exchange

Estimated impacts of ¥1 weaker against US\$ fo Q4 FY2024/3 are as below:

Revenue: +¥57M

Operating profit: +¥38M

Non-operating profit: -¥6M *The impact of foreign exchange fluctuations on non-operating profit is insignificant.

Business Topics:

I. CRO (Nonclinical) Business

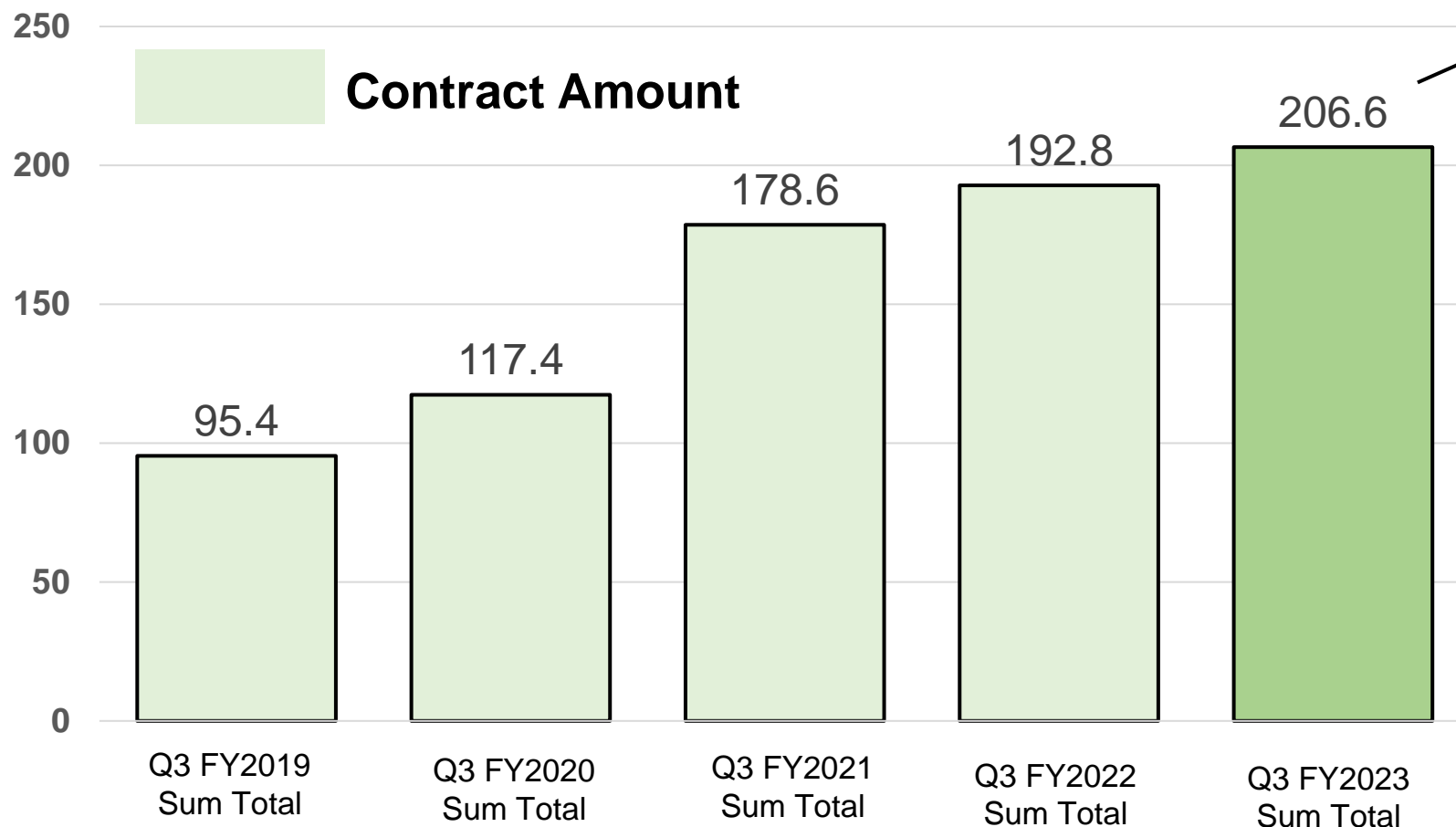


Hideshi Tsusaki, DVM, PhD
Executive Managing Director,
President of Nonclinical Company and Global BD

Contracts Received in Nonclinical Business in Q3 FY2023 (in ¥)



(Units: ¥100M)



Q3 Sum Total YOY +¥1.38B

SNBL +¥1.04B

- Domestic : +¥2.87B
- Overseas : -¥1.83B

INA +¥0.34B

- Domestic : +¥0.49B
- Overseas : -¥0.15B

Exchange rate
(average for the period)
¥143.79/US\$

- * Includes Ina Research from Q2 FY2022
- Overseas contracts are converted to yen using the exchange rate at the end of each period
- Cancelled contracted studies are recorded as a negative figure at the time of cancellation

Order Backlog
at FY end
Overseas
contracts ratio (%)

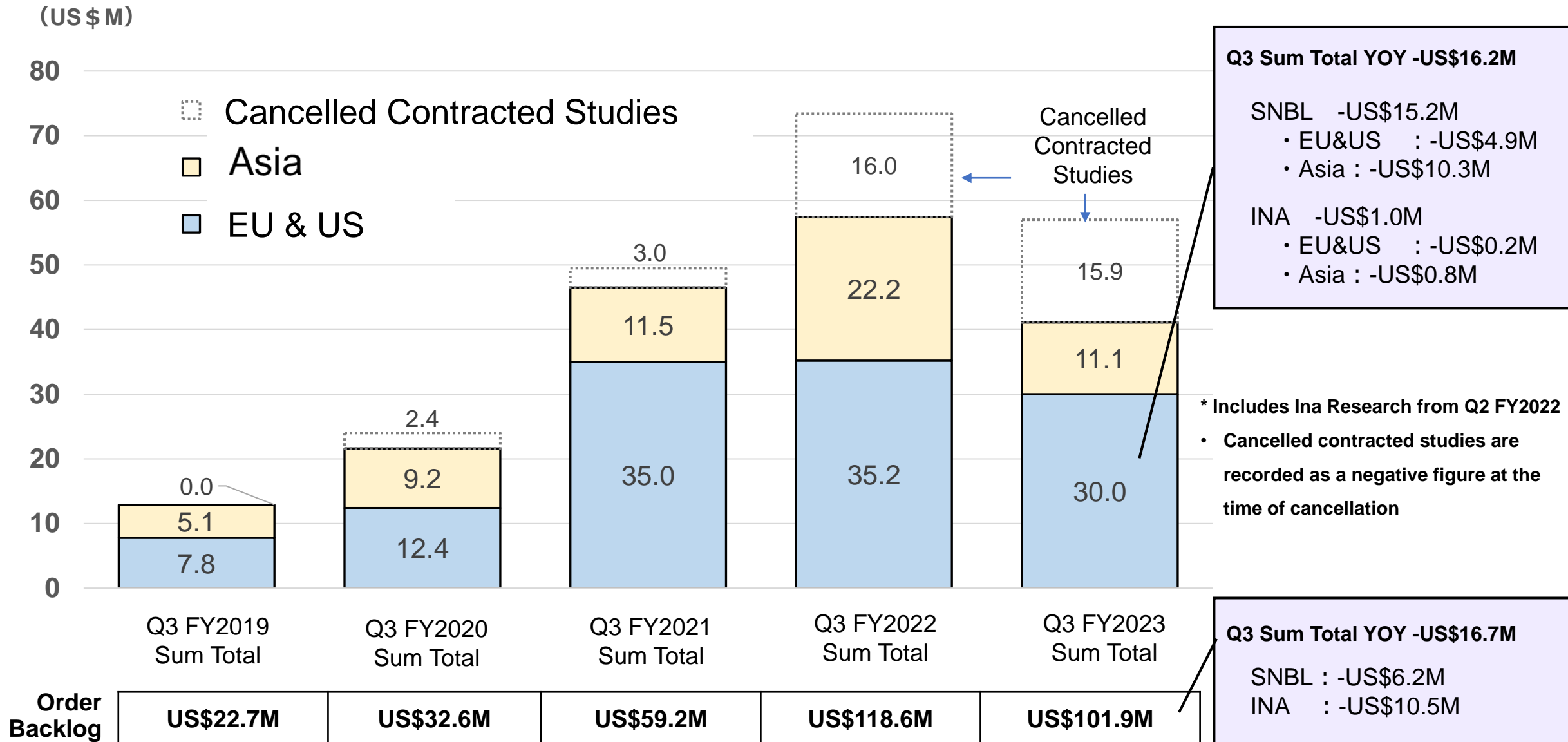
	Q3 FY2019 Sum Total	Q3 FY2020 Sum Total	Q3 FY2021 Sum Total	Q3 FY2022 Sum Total	Q3 FY2023 Sum Total
Order Backlog at FY end	¥11.87B	¥13.80B	¥19.95B	¥32.59B	¥33.86B
Overseas contracts ratio (%)	14.7%	19.4%	29.0%	41.0%	28.7%

Q3 Sum Total YOY +¥1.27B

SNBL : +¥2.81B

INA : -¥1.54B

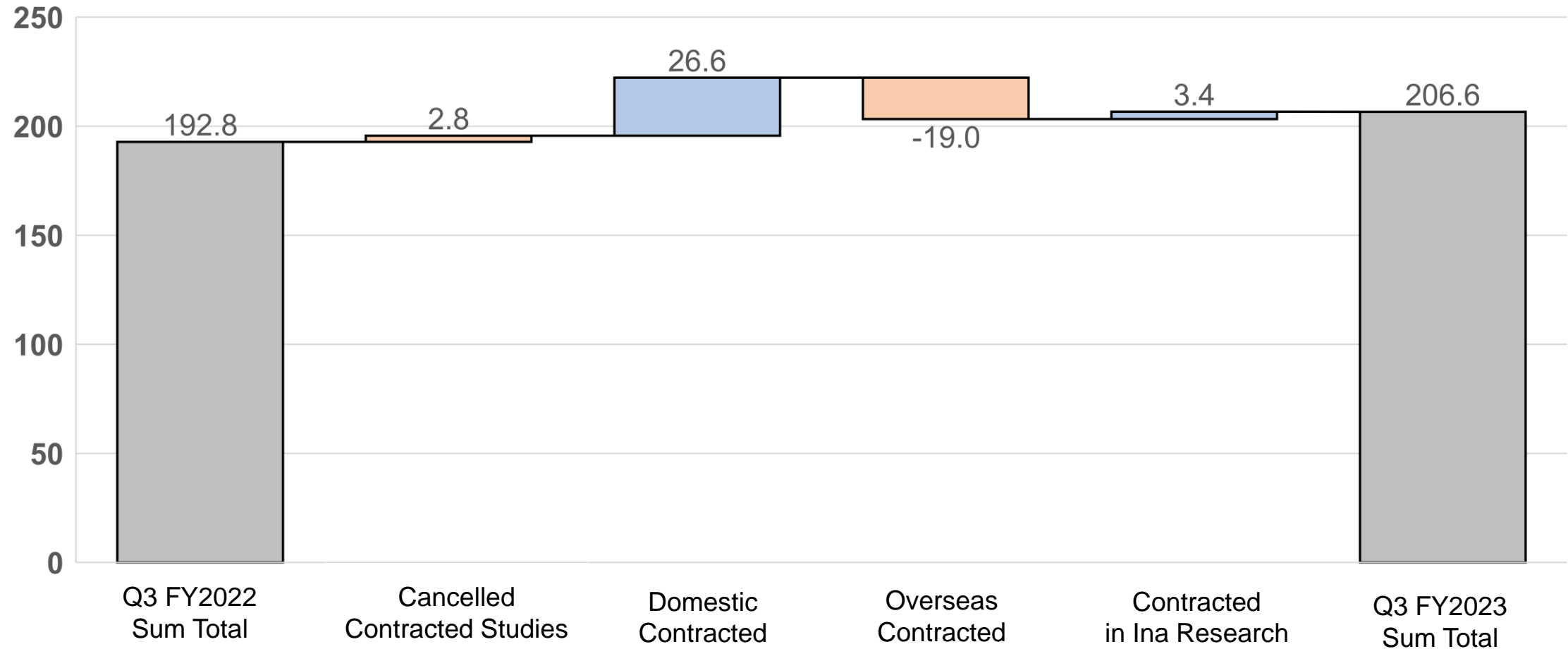
Contracts Received (Overseas) in Nonclinical Business in Q3 FY2023 (in US\$)

Analysis of the Contracts Received in Q3 FY2023



(Units: ¥100M)



Cancelled Contracted Studies: ¥2.88B (Q3 FY2022) -> ¥2.60B (Q3 FY2023)

Domestic

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.

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.

Topics in Q3 FY2023 in Nonclinical Business



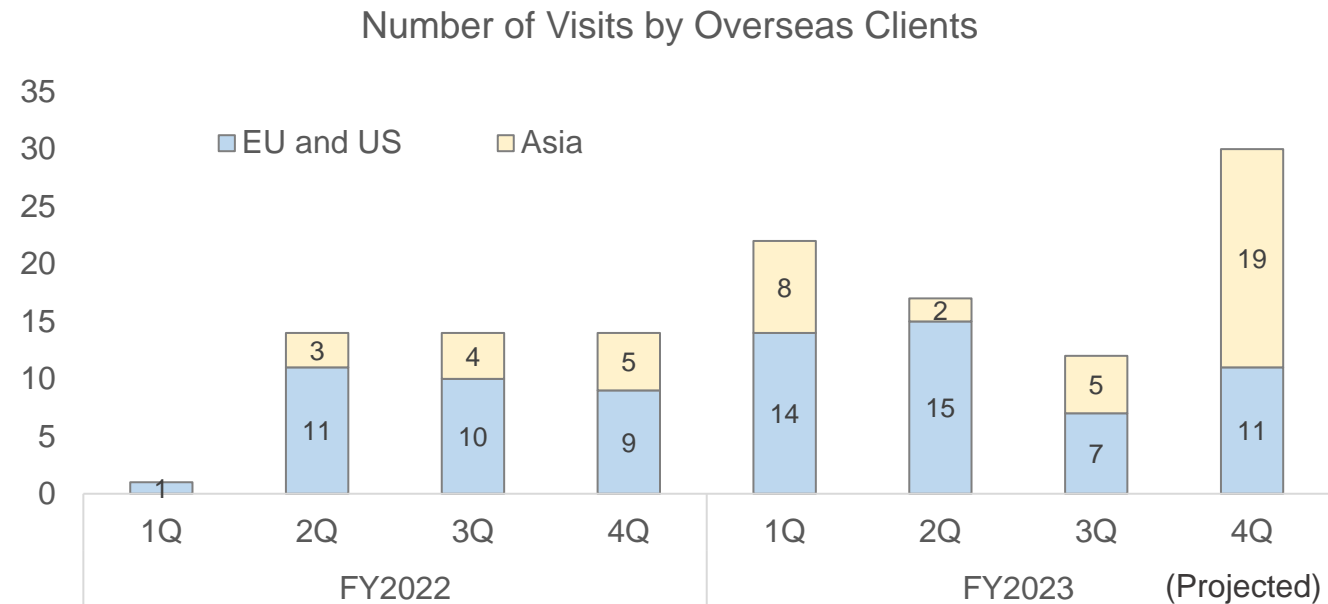
Overseas

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.

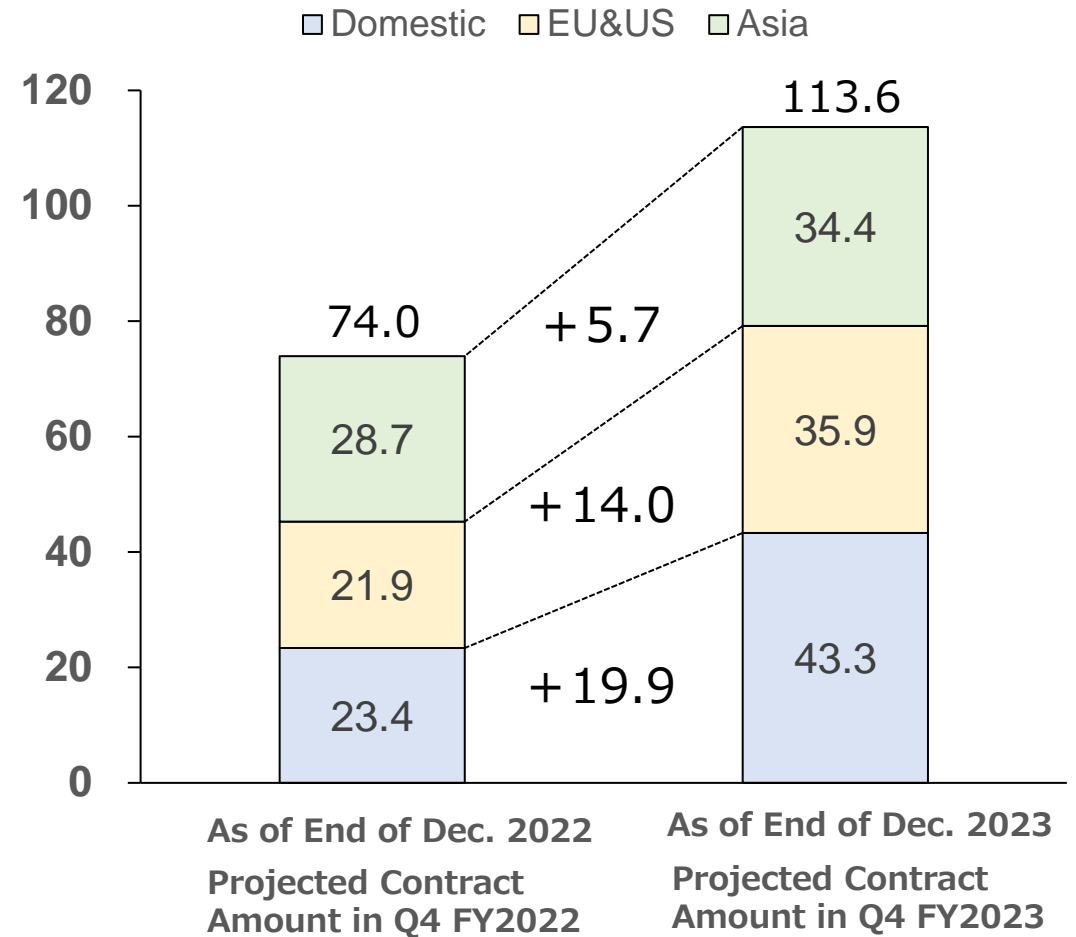
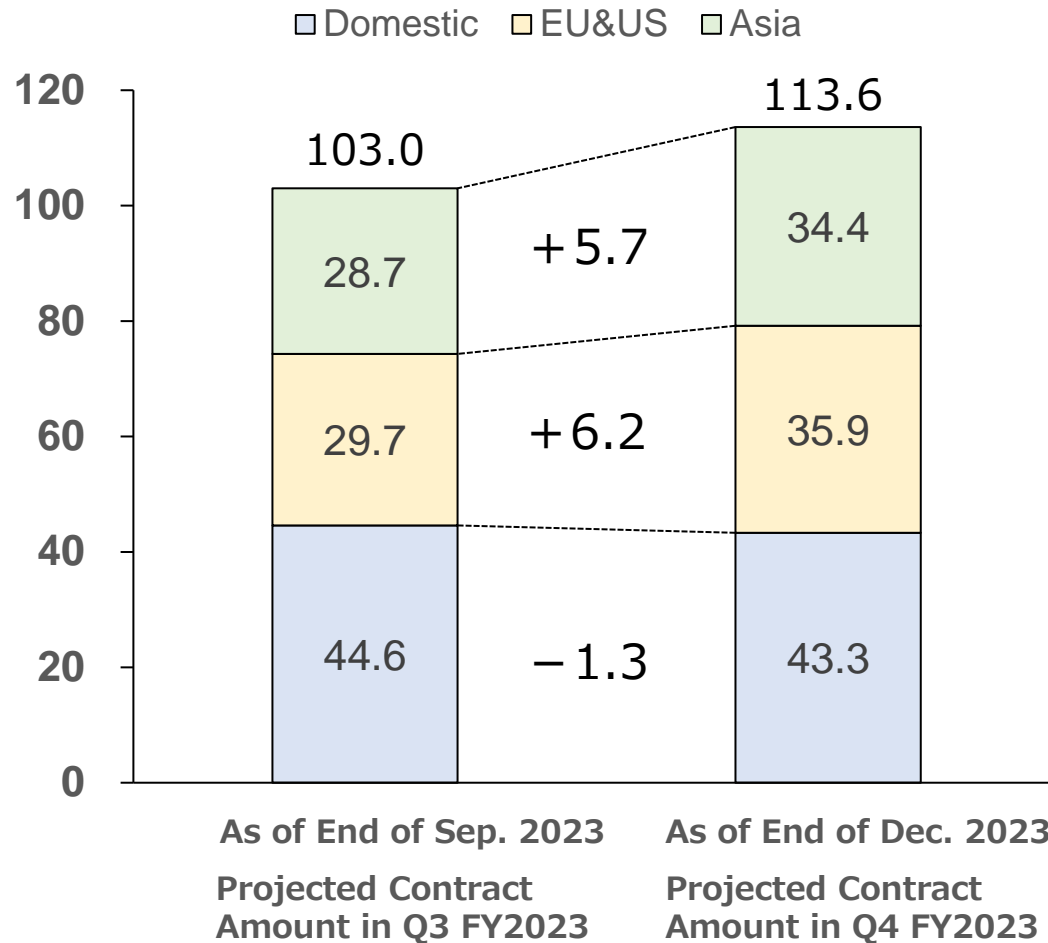


Inquiries in Q3 FY2023 in Nonclinical Business



* Overseas inquiries are converted to ¥ using the average rate for each period.

(Units: ¥100M)



Increase in inquiries (contracted and in discussions) for studies scheduled for contract in Q4 FY2023 as of the end of Dec. 2023

Business Topics:

II. Satsuma Pharmaceuticals and STS101



Ken Takanashi, MBA, CPA
Senior Executive Vice President

For Systemic Absorption



For relief acute migraine



Jan2024:
Issued the Complete Response Letter by the FDA

Early Mar2024:
Will have a meeting with the FDA



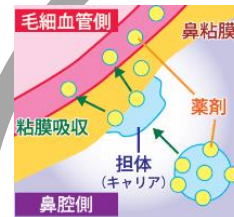
For improvement the wearing-off in Parkinson disease



Aug2023:
Submitted a notification of clinical Phase II trial plan to the PMDA

Jan2024:
Submitted a notification of clinical Phase I trial plan for an improved formulation to the PMDA

SNBL's Proprietary Nasal Drug Delivery System



Nasal Drug Carrier

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

For Vaccination to Enable Blocking Immunity

Nasal Delivery Device

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



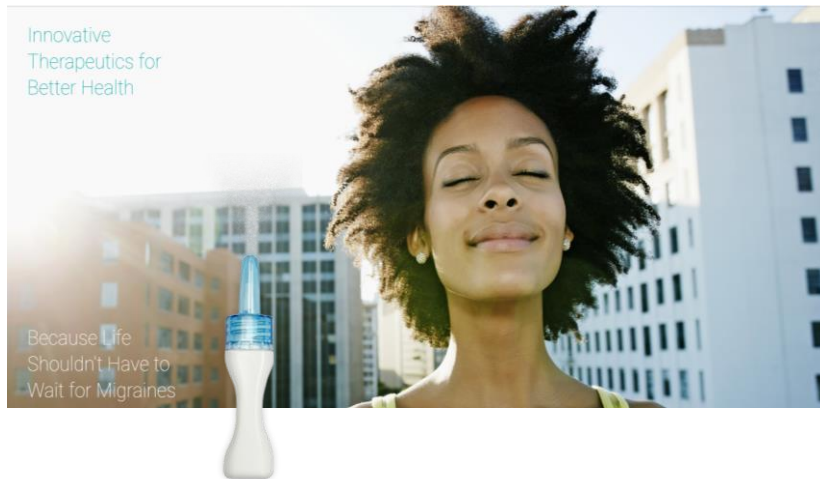
For Nose-to-Brain Delivery

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



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

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

Jan 17, 2024 (US)

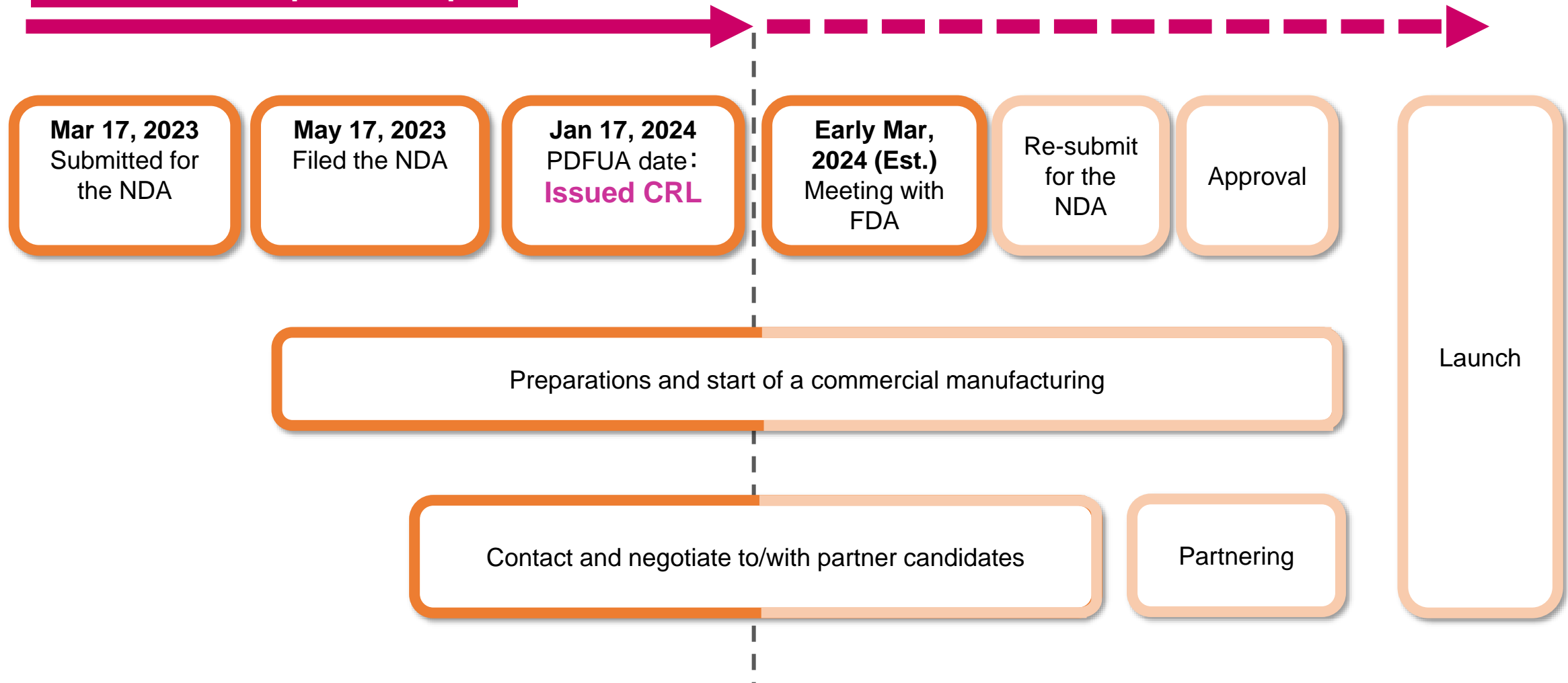
FDA Issued Complete Response Letter (CRL) for STS101

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

Based on results of an FDA meeting that will be had on around early March 2024, Satsuma will plan a re-submission for the NDA of STS101.

TR Business: STS101 Development Steps

[STS101 Development Steps]





Financial Data

(In millions of yen)	2019/3	2020/3	2021/3	2022/3	2023/3	2024/3 Forecasts
Revenue	15,658	14,561	15,110	17,748	25,090	26,190
YoY(%)	-5.7%	-7.0%	3.8%	17.5%	41.4%	4.4%
Gross profit	6,177	7,615	7,554	9,687	13,046	14,167
Ratio of gross profit to revenue (%)	39.5%	52.3%	50.0%	54.6%	52.0%	54.1%
Operating profit	829	2,228	2,529	4,195	5,245	3,470
YoY(%)	-	168.5%	13.5%	65.9%	25.0%	-33.8%
Share of profit of entities accounted for using equity method	361	888	846	1,439	2,489	--
Ordinary profit	1,613	3,121	3,645	7,078	9,194	6,390
Profit before income taxes	1,650	3,062	4,175	8,183	7,759	--
Income taxes	-308	414	497	1,016	1,708	--
Profit attributable to owners of parent	1,950	2,550	3,661	7,127	6,060	3,975
Profit per share (yen)	46.84	61.25	87.95	171.20	145.56	95.47
Overseas sales	4,015	2,317	2,100	3,091	6,575	--
Overseas sales ratio	25.6%	15.9%	13.9%	17.4%	26.2%	--
Revenue from international sponsors	9,958	12,386	15,840	22,181	25,751	--
Net assets	28,477	16,381	15,838	19,723	26,359	--
Total assets	54,329	39,002	36,972	39,312	57,242	--
Interest-bearing debt	16,158	15,123	12,864	9,281	18,931	--
Equity ratio (%)	52.3%	41.8%	42.6%	49.8%	45.8%	--
Capital expenditures	1,612	1,514	1,025	1,703	5,614	10,887
Depreciation	1,361	1,229	1,187	1,177	1,544	1,983
R&D expenses	339	400	392	425	683	1,975
Ratio of R&D expenses to revenue (%)	2.17%	2.75%	2.59%	2.39%	2.72%	7.54%
Number of employees at the end of the fiscal year	935	985	986	994	1,208	1,382
ROE (%)	7.1%	11.4%	22.9%	40.4%	26.5%	--
ROA (%)	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 (%)	5.3%	15.3%	16.7%	23.6%	20.9%	13.2%
Ratio of ordinary profit to revenue (%)	10.3%	21.4%	24.1%	39.9%	36.6%	24.4%
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%	52.4%

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 First Nine 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.

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