

**Financial Results  
for the Second Quarter  
Ended September 30, 2022**

**TAKARA BIO INC.**

**November 15, 2022**

This is an English translation from Japanese presentation material.

## **Contents**

- **Consolidated Financial Results for the Second Quarter Ended September 30, 2022**
- Consolidated Financial Forecast for the Year Ending March 31, 2023
- Business Progress and Future Measures

# Consolidated Quarterly Financial Results for FY2023 (for the 2<sup>nd</sup> Quarter Ended September 30, 2022)

(million yen)	Actual	Y/Y	Comparison with May 12 forecast
<b>Net sales</b>	<b>32,587</b>	<b>+1,035 +3.3%</b>	<b>+4,842 +17.5%</b>
Reagents <sup>[1]</sup>	27,565	+2,576 +10.3%	+4,989 +22.1%
Instruments	694	▲17 ▲2.5%	+25 +3.8%
CDMO	3,183	▲1,548 ▲32.7%	▲121 ▲3.7%
Gene Therapy <sup>[2]</sup>	1,144	+26 +2.3%	▲50 ▲4.2%
<b>Gross profit</b>	<b>22,025</b>	<b>▲1,470 ▲6.3%</b>	<b>+2,338 +11.9%</b>
<b>Operating profit</b>	<b>10,870</b>	<b>▲3,234 ▲22.9%</b>	<b>+2,228 +25.8</b>
<b>R&amp;D</b>	<b>3,853</b>	<b>+1,193 +44.9%</b>	<b>+122 +3.3%</b>

(Explanation of Y/Y changes)

- **Reagents:** Grew in sales of COVID testing-related reagents, while sales of general research reagents remained firm.
- **Instruments:** Sales of PCR equipment and single-cell analysis equipment remained the same level as the previous fiscal year.
- **CDMO:** Lower sales related to COVID vaccines and large-scale genome analysis projects
- **Gene therapy:** Sales of GMP grade reagents increased.
- **Operating profit:** Gross profit declined due to product mix and other factors. Operating profit decreased due to aggressive investment in R&D, etc.

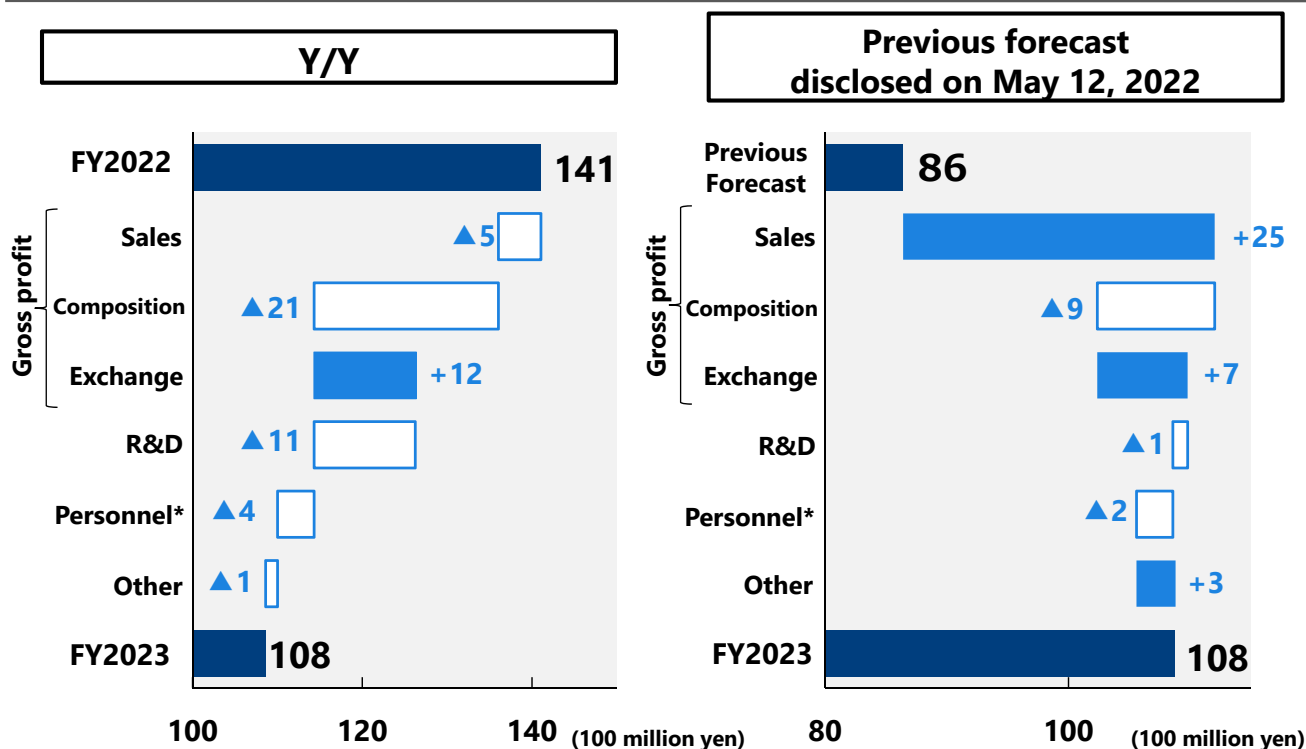
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[1] Including in vitro diagnostics

[2] Sales of GMP grade reagents, were reclassified from "Reagents" to "Gene Therapy" from the fiscal year under review.



## The 2<sup>nd</sup> Quarter; Operating Profit



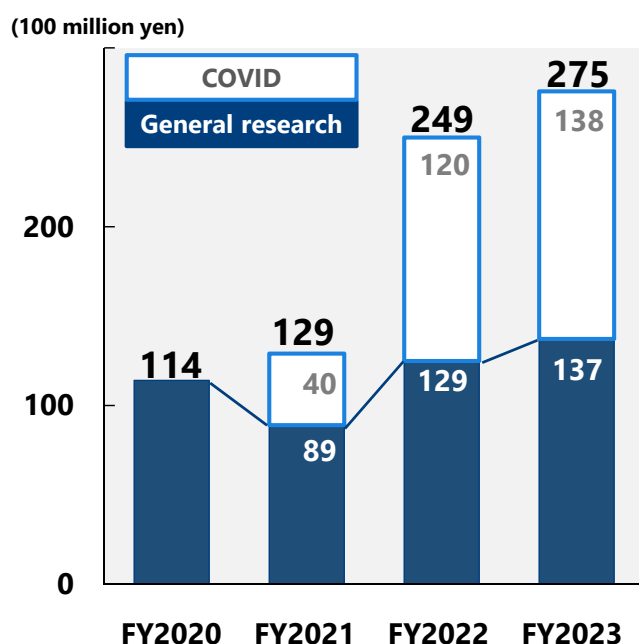
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\* Excluding R&D personnel expenses

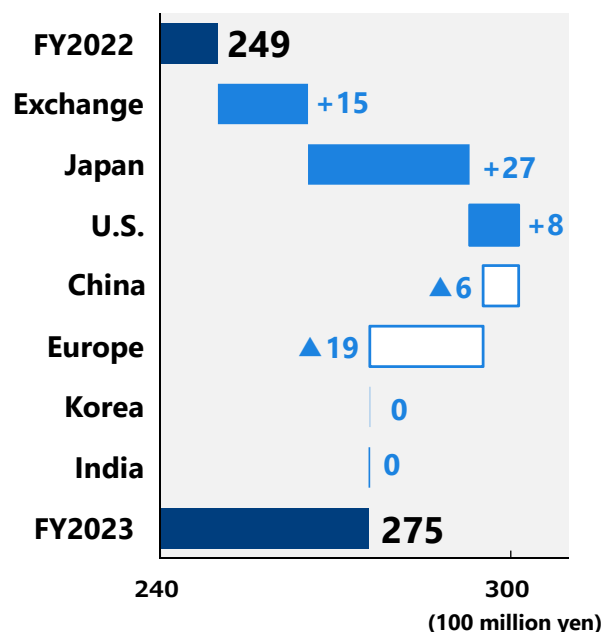


## The 2<sup>nd</sup> Quarter; Reagents

### Actual net sales



### Sales performance by region



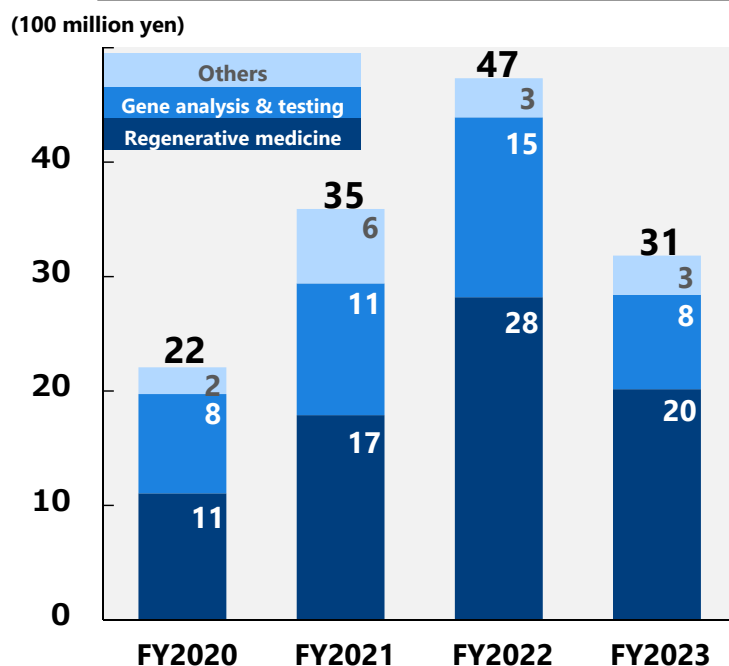
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Graphs are displayed reflecting the reclassification of sales of GMP grade reagents, etc.



## The 2<sup>nd</sup> Quarter; CDMO

### Actual net sales



### Regenerative medicine

- Sales decreased due to a decline in COVID vaccine-related contracts, despite robust sales of vector production, cell processing, and quality testing

### Gene analysis and testing

- Decreased in sales due to the impact of the completion of large-scale genome analysis projects such as human whole genome analysis.

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## Consolidated Financial Forecast for FY2023 (for the Year Ending March 31, 2023)

(millions yen)	FY2023 Full-year	Y/Y	Comparison with May 12 forecast
<b>Net sales</b>	<b>77,800</b>	<b>+10,100 +14.9%</b>	<b>+22,500 +40.7%</b>
Reagents <sup>[1]</sup>	65,106	+12,626 +24.1%	+24,095 +58.8%
Instruments	1,716	+197 +13.0%	+244 +16.6%
CDMO	8,356	▲3,070 ▲26.9%	▲1,855 ▲18.2%
Gene Therapy <sup>[2]</sup>	2,621	+346 +15.2%	+15 +0.6%
<b>Gross profit</b>	<b>43,731</b>	<b>▲5,480 ▲11.1%</b>	<b>+5,875 +15.5%</b>
<b>Operating profit</b>	<b>19,000</b>	<b>▲9,902 ▲34.3%</b>	<b>+4,000 +26.7</b>
<b>R&amp;D</b>	<b>8,713</b>	<b>+2,604 +42.6%</b>	<b>+893 +11.4%</b>

(Explanation of Y/Y changes)

- **Reagents:** Significant growth in COVID testing-related reagents, steady growth in general research reagents
- **Instruments:** PCR equipment sales down slightly, single-cell analysis equipment sales up
- **CDMO:** COVID vaccine-related contract and large-scale genome analysis project-related contract sales decreased
- **Gene Therapy:** Sales of GMP grade reagents increased
- **Operating profit:** Gross profit decreased due to product mix and other factors. Operating income decreased due to aggressive investment in R&D, etc.

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[1] Including in vitro diagnostics

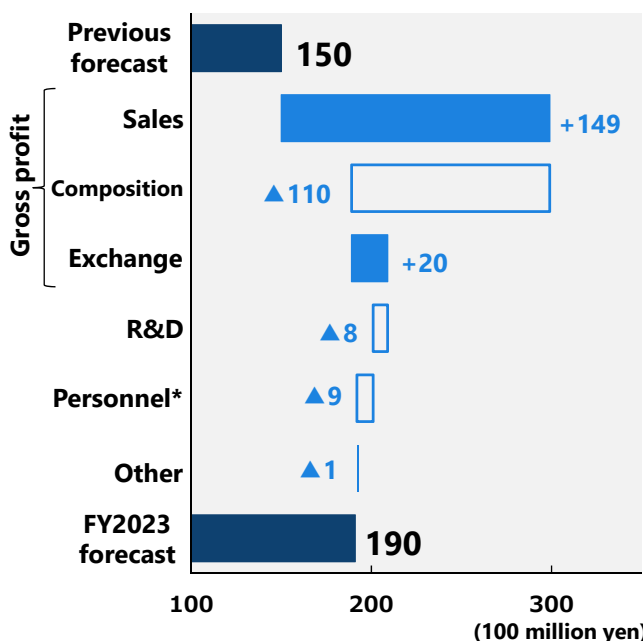
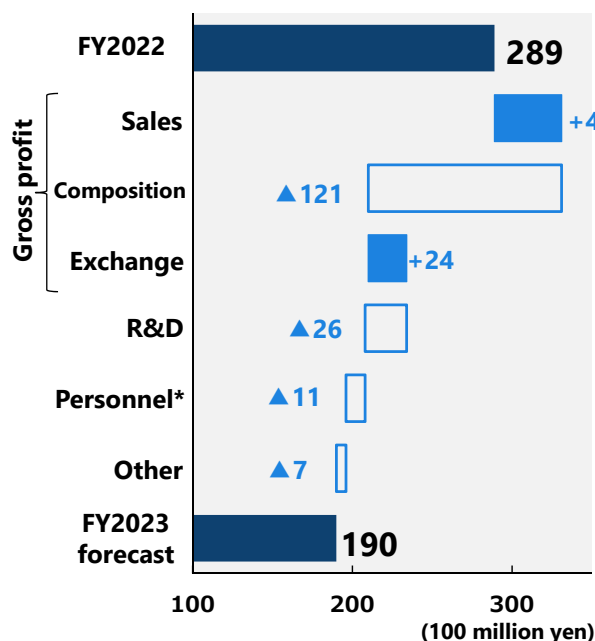
[2] Sales of GMP grade reagents, were reclassified from "Reagents" to "Gene Therapy" from the fiscal year under review.



# Full-year Forecast; Operating Profit

Y/Y

Previous forecast  
disclosed on May 12, 2022



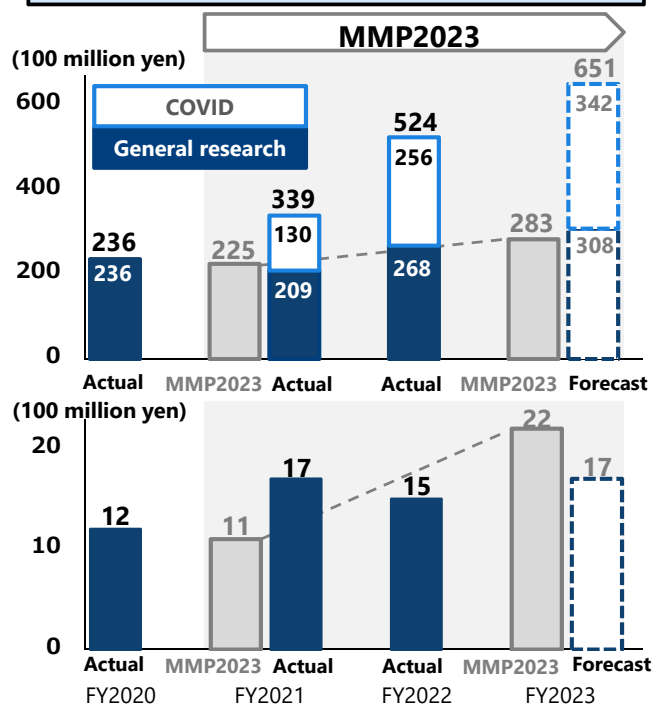
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\* Excluding R&D personnel expenses



# Full-year Forecast; Reagents and Instruments

## Actual Net Sales and Forecast



## Reagents

- **COVID:** In addition to PCR diagnostic reagents, sales are expected to increase significantly due to a significant contribution from antigen testing kits.
- **General research:** Overall sales are forecast to increase Y/Y, despite regional differences and the impact of foreign exchange rates. Forecast to achieve the final-year targets of the medium-term management plan FY2023 (MMP2023).

## Instruments

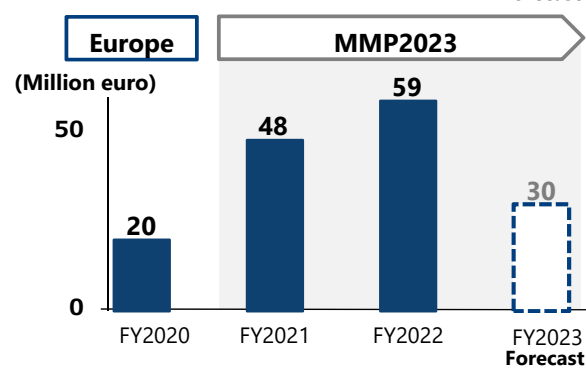
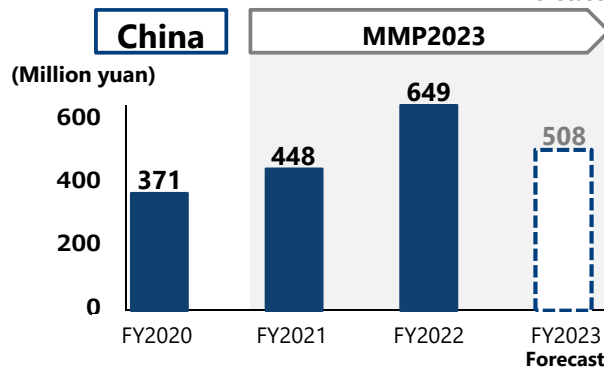
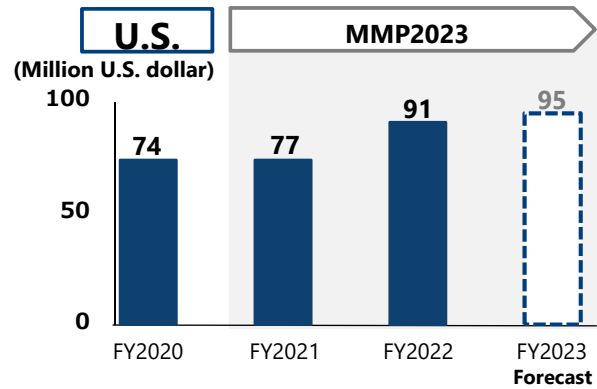
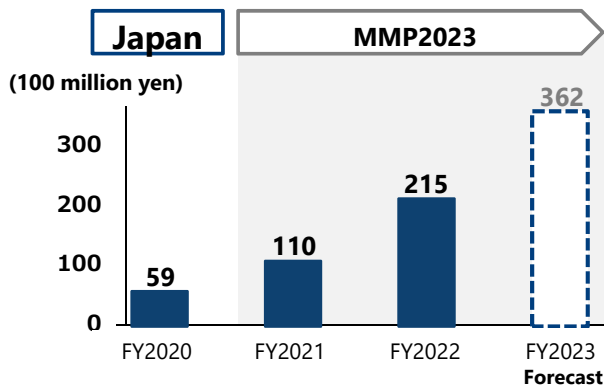
- Sales of PCR equipment was consistent with the preceding period due to COVID testing-related demand and other factors. Expected to increase overall sales due to growth in single-cell analysis-related equipment.
- Targets for the final year of the MMP2023 are not expected to be achieved.

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Graphs are displayed reflecting the reclassification of sales of GMP grade reagents, etc.



# Full-year Forecast; Sales for Reagents by Region

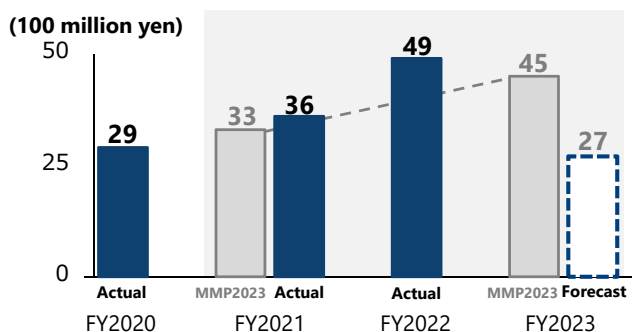
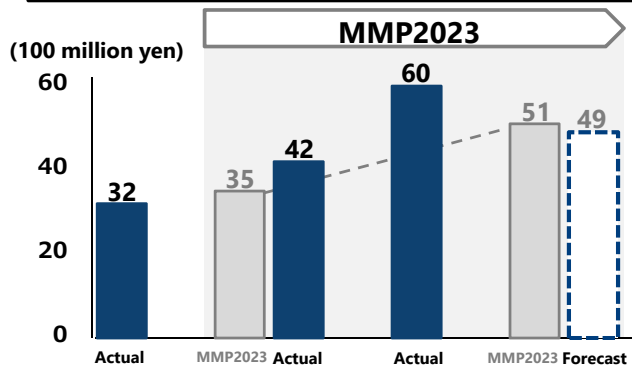


10 MMP2023: Medium-Term Management Plan FY2023



# Full-year Forecast; CDMO

## Actual Net Sales and Forecast



## Regenerative Medicine

- Despite robust sales of vector production, cell processing, and quality testing, overall sales are expected to decrease due to a decline in contracts for COVID vaccine-related projects
- Progress of some projects is also delayed, and the targets for the final year of the MMP2023 are expected to not be achieved

## Gene Analysis and Testing

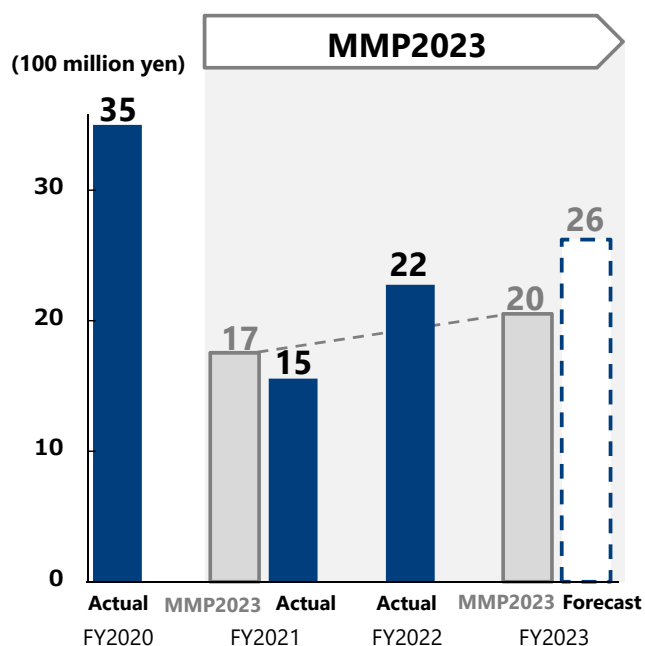
- The impact of the completion of large-scale genome analysis projects, such as human genome analysis, is significant, and sales are expected to decline significantly Y/Y, and the targets for the final year of the MMP2023 are also expected to not be achieved.

11 MMP2023: Medium-Term Management Plan FY2023



# Full-year Forecast; Gene Therapy

## Actual Net Sales and Forecast



- Strong sales of RetroNectin®, which is the worldwide standard for gene transducing methods to T-cells, etc., as CAR-T gene therapies have become more active in clinical development and more popular overseas.
- Due to the strong demand for RetroNectin®, significant increase in capacity for the production at the Center for Gene and Cell Processing (CGCP).
- Plan to launch a succession of enzymes for the production of mRNA vaccines as GMP grade reagents.
- Anticipate decreasing in consideration fees for gene therapy projects.

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Graphs are displayed reflecting the reclassification of sales of GMP grade reagents, etc.  
MMP2023: Medium-Term Management Plan FY2023



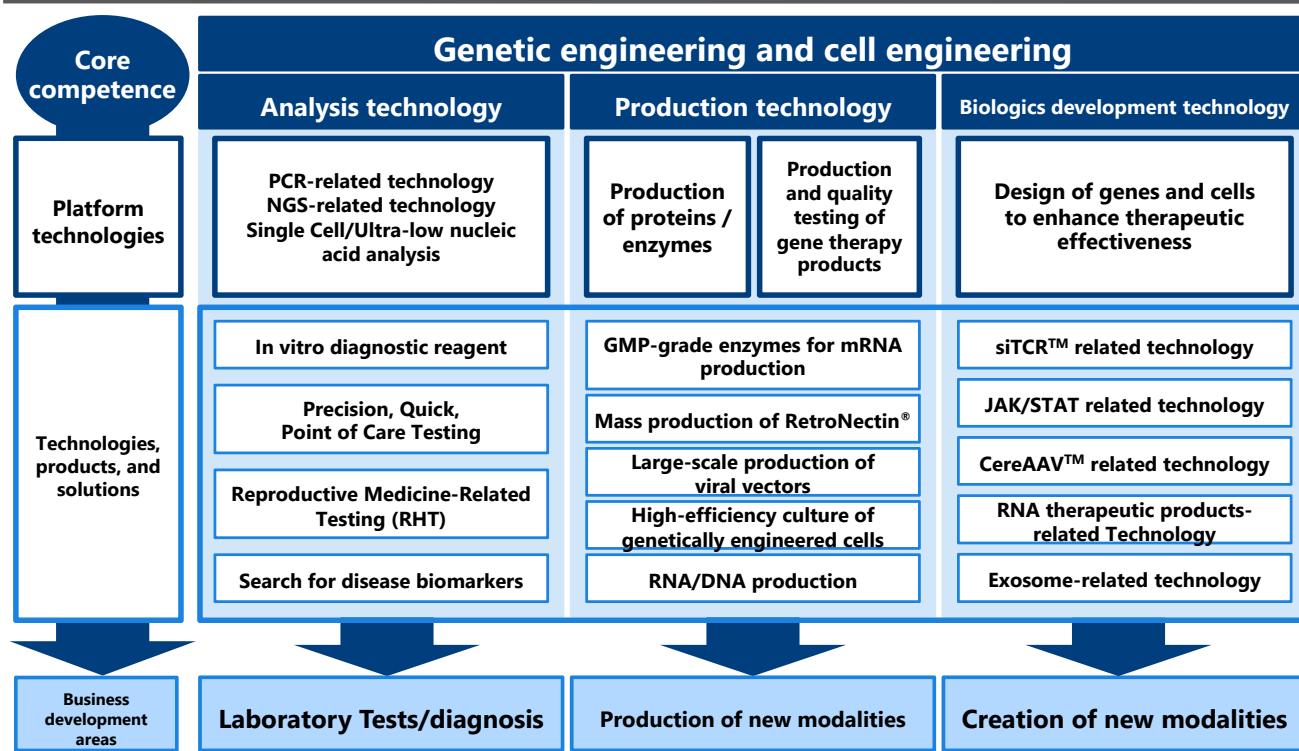
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# Direction of Business and R&D: Aiming for growth by providing value to clinical and biologics development fields based on unique platform technologies

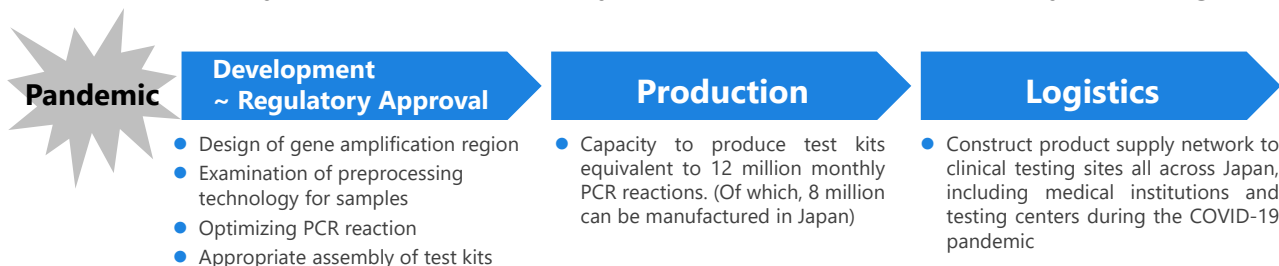


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## Established a system for rapidly developing and supplying PCR testing related products Flexible response to rapidly expanding demand due to the outbreak of infectious diseases

- Build superiority across the entire supply chain, in addition to proprietary technologies



- Continuously improving and expanding the lineup of PCR for the detection of infectious diseases

- Launched detection kits for Adenoviruses Types 40 / 41, and Monkeypox virus
- Improving the performance of Norovirus genotype classification kits
- Launched reagents for the detection of new variants of new Coronavirus
- Renewal of existing models of PCR related equipment and development of new models for on-site (sample collection site) testing



"Clontech PCR Thermal Cycler GP"  
Compact PCR device  
Launched in October, 2022

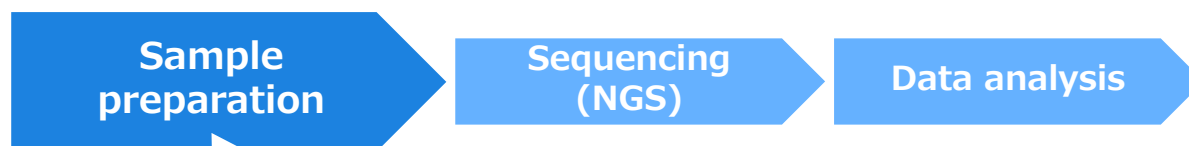
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## NGS analysis business will be shifted to developing high-value-added products/services based on proprietary technologies

### Process of Next-Generation Sequencing (NGS) Analysis



Focus on the development of new reagents and systems that will be useful for preparation for sequencing, etc.

#### Expanding into high-value-added applications in the field of clinical diagnostics and testing

- Support for reproductive health testing (RHT)
- Support for biomarker searching and testing such as for cancer and infectious diseases
- Support for exploratory research and clinical development of pharmaceutical companies, etc.

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## Termination of co-development and exclusive marketing agreements with Otsuka Pharmaceutical Co., Ltd. for NY-ESO-1 · siTCR™ gene therapy candidate

### Target Item: NY-ESO-1 · siTCR™

(Development Code: TBI-1301, INN: mipetresgene autoleucel)

- Target agreement: Agreement for Co-Development and Marketing of NY-ESO-1 · siTCR™ Gene Therapy Product (Concluded April 9, 2018)
- Reasons for the termination: Takara Bio Inc. (Takara Bio) and Otsuka Pharmaceutical Co. Ltd. (Otsuka) have been jointly developing NY-ESO-1 · siTCR™ gene therapy for synovial sarcoma in Japan, and preparing for submission for manufacturing and marketing approval. However, after comprehensive discussions between the two companies on policies and strategies related to the product, Takara Bio and Otsuka have agreed to terminate this agreement. This decision is not due to any efficacy or safety issues of the product.
- Details of the termination agreement: Technical, intellectual property and other rights related to product are returned to Takara Bio.

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# The CGCP II moves into the final implementation stage

Promoting the strengthening of production technology capabilities and the systems

## ● Complete implementation of Building 2 of the CGCP (CGCP II)

### • Expansion of cell processing room (scheduled to start operation in 2023)

- ✓ Proprietary Isolators (for cell processing and filling) installed, guaranteeing the highest level of aseptics
- ✓ In addition to autologous cells, respond to large-scale production of allogeneic cells
- ✓ Collaborate with digital tools to strengthen quality assurance of data and improve productivity

### • Expansion of Virus Vector Production Facility (scheduled to start operation in 2023)

- ✓ Introduced 2,000 L suspension cell culture system. Compatible with commercial production of AAV vectors, etc.



## ● Strengthen production technology

- ✓ Promoting the development of elemental technologies necessary for mass production of virus vectors and gene transduced cells
- ✓ Focus on developing production processes for mRNA in addition to cell/gene therapy products

## ● Strengthen production and quality assurance systems

- ✓ Strengthening technical training and education/training programs to improve productivity of GMP/GCTP production and strengthen quality assurance systems

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# Selected for METI's "Developing biopharmaceutical manufacturing sites to strengthen vaccine production project"

## ● Plan to build the **third** building of the CGCP (CGCP III)

- Building area: approx. 2,650 m<sup>2</sup>
- Floor space: approx. 16,400 m<sup>2</sup>
- Structure: 7-story seismic isolation structure
- Construction started: April 2024 (plan)
- Final completion: June 2027 (plan)

## ● "Dual-use" facilities to produce vaccines in emergencies and use them in CDMO businesses in normal times



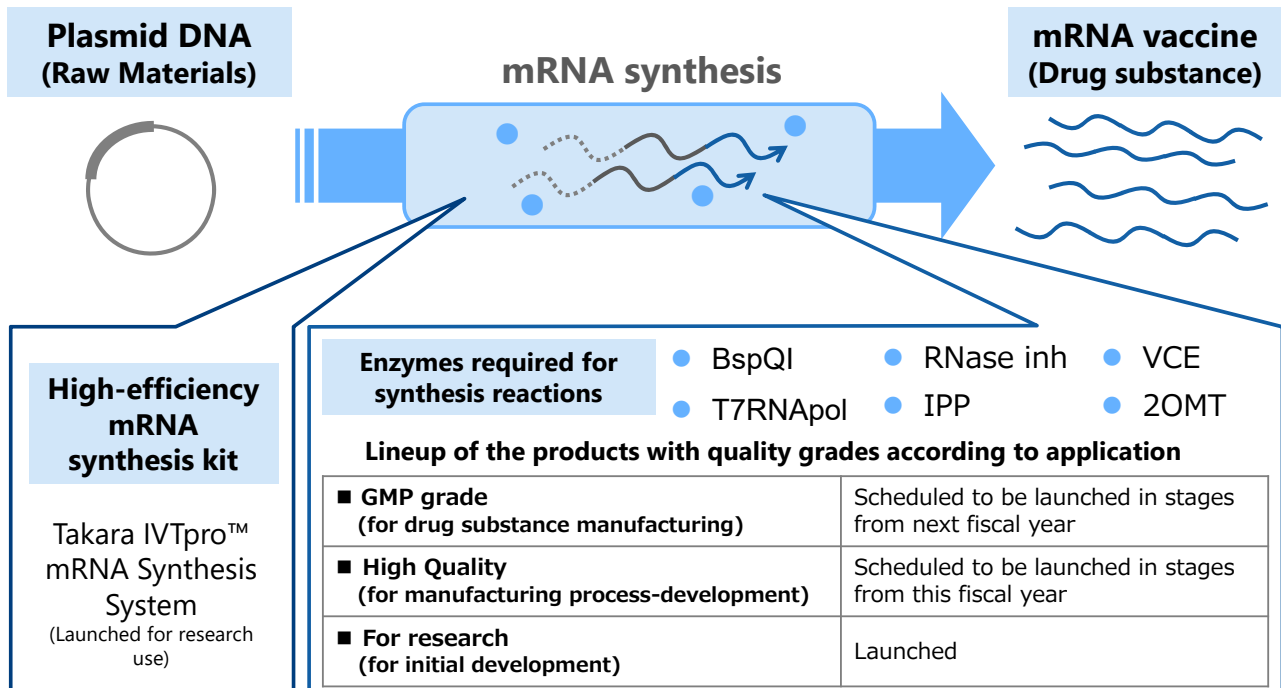
Our adoption projects	Items produced in normal times	Items produced in an emergency
1. Vaccine production site	Various viral vectors for gene therapy mRNA drug substance	Viral vector vaccine mRNA vaccine
2. Materials production site	RetroNectin®, mRNA production enzymes and other GMP grade reagents	Enzymes for mRNA production

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METI: Japan's Ministry of Economy, Trade and Industry



## Providing comprehensive solutions including enzymes for production in addition to GMP manufacturing in mRNA



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## Focus on maximizing the value of our proprietary technologies for biologics development

### ● ex vivo gene therapy project

- NY-ESO-1·siTCR™ (TBI-1301) :  
Application for approval in Japan for synovial sarcoma
- CD19·JAK/STAT·CAR (TBI-2001) :  
Canadian clinical trials for hematologic cancers
- Developing JAK/STAT · CAR for solid oncology therapy applications

### ● in vivo gene therapy project

- Developed for therapeutic applications of CereAAV™, a cerebral-oriented AAV vector
- Develop new AAV variants with new organizational orientations, etc.

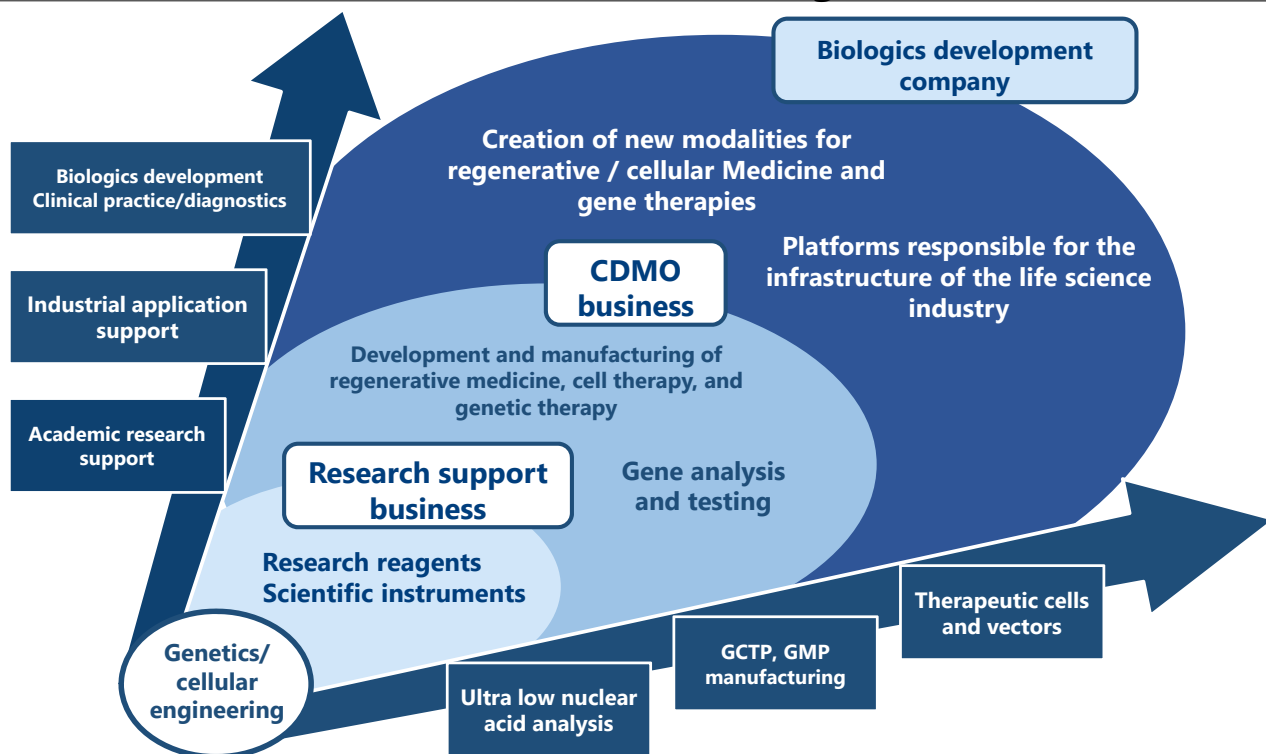
### ● Initiatives to create new modalities other than gene therapy

- Establishment of sponsored laboratory on Exosome and other topics in Faculty of Medicine, the University of Tokyo

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# Realizing Sustainable Growth through "R&D Support Business" and "CDMO Business" driven by the Development of Platform Technologies



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## Forward-looking Statements

Statements in this news release, other than those based on historical fact, concerning the current plans, prospects, strategies and expectations of the Company and its Group represent forecasts of future results. While such statements are based on the conclusions of management according to information available at the time of writing, they reflect many assumptions and opinions derived from information that includes major risks and uncertainties. Actual results may vary significantly from these forecasts due to various factors. Factors that could influence actual results include, but are not limited to, economic conditions, especially trends in consumer spending, as well as exchange rate fluctuations, changes in laws and government systems, pressure from competitors' prices and product strategies, decline in selling power of the Company's existing and new products, disruptions to production, violations of our intellectual property rights, rapid advances in technology and unfavorable verdicts in major litigation.

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## Consolidated Financial Results (2Q)

(million yen)

	FY2023 2 <sup>nd</sup> -quarter	Y / Y		Comparison with May 12 forecast	
		Change	Ratio	Change	Ratio
Net sales	32,587	1,035	3.3%	4,842	17.5%
Cost of sales	10,562	2,505	31.1%	2,504	31.1%
Gross profit	22,025	▲1,470	▲6.3%	2,338	11.9%
SG&A expenses	11,154	1,764	18.8%	109	1.0%
Operating profit	10,870	▲3,234	▲22.9%	2,228	25.8%
Ordinary profit	10,955	▲3,285	▲23.1%	2,229	25.6%
Net income attributable to owners of parent	8,538	▲1,470	▲14.7%	2,184	34.4%

【Reference】

## Consolidated Financial Results (Full-year Forecast)

(million yen)

	FY2023 Full-year	Y / Y		Comparison with May 12 forecast	
		Change	Ratio	Change	Ratio
Net sales	77,800	10,100	14.9%	22,500	40.7%
Cost of sales	34,068	15,580	84.3%	16,624	95.3%
Gross profit	43,731	▲5,480	▲11.1%	5,875	15.5%
SG&A expenses	24,731	4,421	21.8%	1,875	8.2%
Operating profit	19,000	▲9,902	▲34.3%	4,000	26.7%
Ordinary profit	19,100	▲9,359	▲32.9%	4,000	26.5%
Net income attributable to owners of parent	13,800	▲6,049	▲30.5%	3,200	30.2%

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【Reference】

## Net Sales by Category (2Q)

(million yen)

	FY2023 2 <sup>nd</sup> -quarter	Y / Y		Comparison with May 12 forecast	
		Change	Ratio	Change	Ratio
Reagents	27,565	2,576	10.3%	4,989	22.1%
Instruments	694	▲17	▲2.5%	25	3.8%
CDMO	3,183	▲1,548	▲32.7%	▲121	▲3.7%
Gene Therapy	1,144	26	2.3%	▲50	▲4.2%
Total net sales	32,587	1,035	3.3%	4,842	17.5%

The sales of GMP-grade reagents and the resembling which are used for manufacturing regenerative medicine products including in "Reagents" until the year ended of March 31, 2022, have been included in "Gene therapy" since the year ending March 31, 2023.

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[Reference]

## Net Sales by Category (Full-year Forecast)

(million yen)

	FY2023 Full-year	Y / Y		Comparison with May 12 forecast	
		Change	Ratio	Change	Ratio
Reagents	65,106	12,626	24.1%	24,095	58.8%
Instruments	1,716	197	13.0%	244	16.6%
CDMO	8,356	▲3,070	▲26.9%	▲1,855	▲18.2%
Gene Therapy	2,621	346	15.2%	15	0.6%
Total net sales	77,800	10,100	14.9%	22,500	40.7%

(28)



[Reference]

## Reagents Sales by Region (2Q)

(million yen)

	FY2023 2 <sup>nd</sup> -quarter	Y / Y (Exchange excluded)	
		Change	Ratio
Japan	12,919	2,765	27.2%
U.S.	6,273	839	18.0%
China	4,979	▲608	▲12.2%
Europe	2,093	▲1,939	▲49.0%
Korea	580	7	1.4%
India	719	▲29	▲4.3%
Total	27,565	1,034	4.1%

(29)



[Reference]

## Reagents Sales by Region (Full-year Forecast)

(million yen)

	FY2023 Full-year	Y / Y (Exchange excluded)	
		Change	Ratio
Japan	36,276	14,759	68.6%
U.S.	12,540	351	3.5%
China	9,913	▲2,407	▲21.7%
Europe	4,136	▲3,761	▲49.0%
Korea	1,215	32	2.9%
India	1,023	▲93	▲9.4%
<b>Total</b>	<b>65,106</b>	<b>8,881</b>	<b>16.9%</b>

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[Reference]

## Performance by Subsidiaries

(million yen)

	2 <sup>nd</sup> -quarter Actual		Full-year Forecast	
	Net sales	Operating profit	Net sales	Operating profit
Takara Bio (Non-consolidated)	22,483	7,568	57,432	13,770
Takara Bio Europe (Consolidated)	2,441	254	4,924	241
Takara Biotechnology (Dalian)	2,831	897	5,491	1,488
Takara Biomedical Technology (Beijing)	5,382	869	10,766	1,575
Takara Korea Biomedical	730	112	1,433	227
DSS Takara India	730	81	1,047	48
Takara Bio USA	8,616	1,864	17,471	2,521

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# Exchange Rate

(Unit: Yen)	FY2022 2 <sup>nd</sup> -quarter	FY2022 Full-year	FY2023 2 <sup>nd</sup> -quarter	FY2023 Full-year
	Actual	Actual	Actual	Forecast
US dollar	107.82	109.90	123.15	131.80
Euro	129.88	129.91	134.39	137.00
Yuan	16.67	17.04	18.97	19.50
100 Won	9.64	9.60	9.97	10.20
Rupee	1.47	1.49	1.62	1.70
Sweden Krona	12.82	12.81	12.82	13.10
Pound	149.78	151.17	159.58	158.60