



**Financial Results Presentation
for the second Quarter
Ended September 30, 2021**

TAKARA BIO INC.
November 11, 2021

This is an English translation from Japanese presentation material.

Contents

- **Consolidated Quarterly Financial Results for FY2022 (for the Second Quarter Ended Sep. 30, 2021)**
- Consolidated Financial Forecast for FY2022
- Business Progress and Future Measures

Consolidated Quarterly Financial Results for FY2022 (for the Second Quarter Ended Sep. 30, 2021)

(million yen)	FY2022 2 nd -quarter	Y/Y	Comparison with Aug.3 forecast
Net Sales	31,551	+14,158 +81.4%	+1,851 +6.2%
Reagents	25,966	+12,629 +94.7%	+1,908 +7.9%
Instruments	712	+245 +52.6%	▲78 ▲9.9%
CDMO	4,732	+1,358 +40.3%	+5 +0.1%
Gene therapy	140	▲75 ▲35.0%	+16 +13.4%
Gross profit	23,495	+11,667 +98.6%	+2,544 +12.1%
Operating profit	14,105	+10,368 +277.5%	+2,705 +23.7%

Reagents

Growth in the new Coronavirus PCR test-related product. Reagents for general research are recovering

Instruments

Strong sales of PCR instrument.

CDMO

Increased in revenue for Regenerative Medicine, Gene Analysis and Testing, and Vaccine on CDMO

Gene therapy

Decrease in sales of investigational products

Gross profit

Increased due to higher sales and improvement in the profitability of CDMO

Operating profit

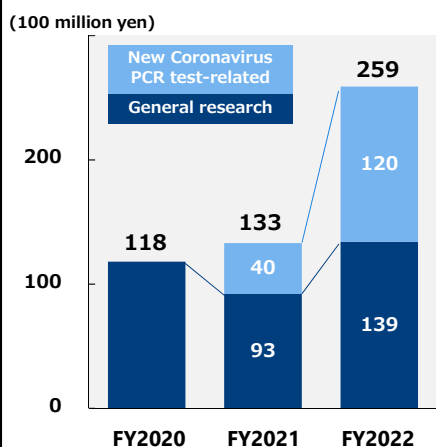
Despite an increase in general and administrative expenses, the increase in gross profit was significant, resulting in an increase in profits.

3 (NOTE) Explanation of year-on-year changes

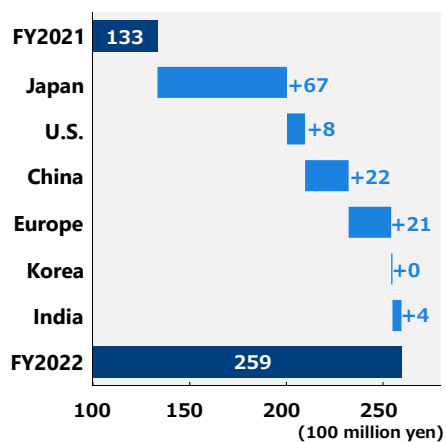


2nd Quarter Ended Sep. 30, 2021: Sales for Reagents

Sales Breakdown



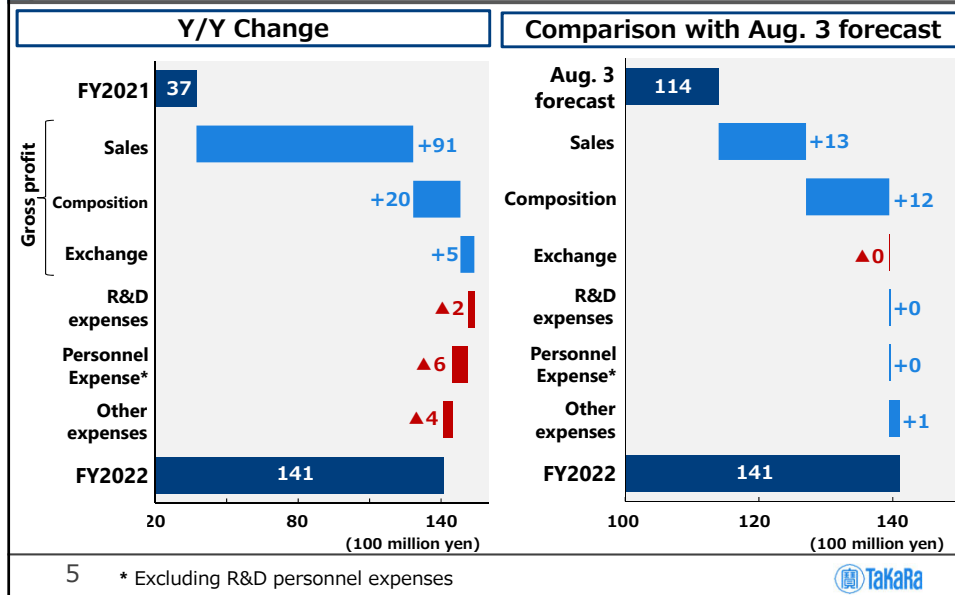
Sales Breakdown by Region



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2nd Quarter Ended Sep. 30, 2021; Operating Profit




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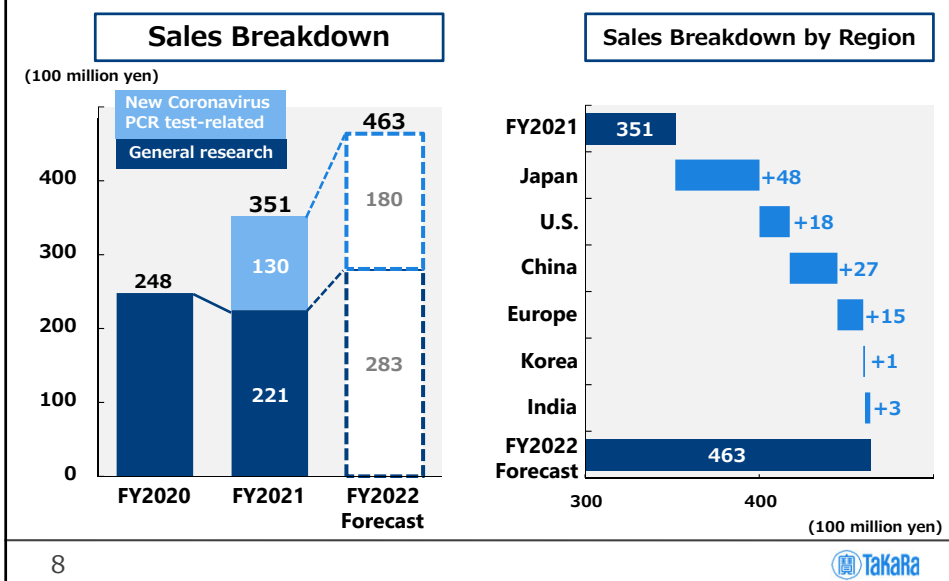
- Consolidated Quarterly Financial Results for FY2022 (for the Second Quarter Ended Sep. 30, 2021)
- **Consolidated Financial Forecast for FY2022**
- Business Progress and Future Measures

Consolidated Financial Forecast for FY2022 (for the Year Ending March 31, 2022)

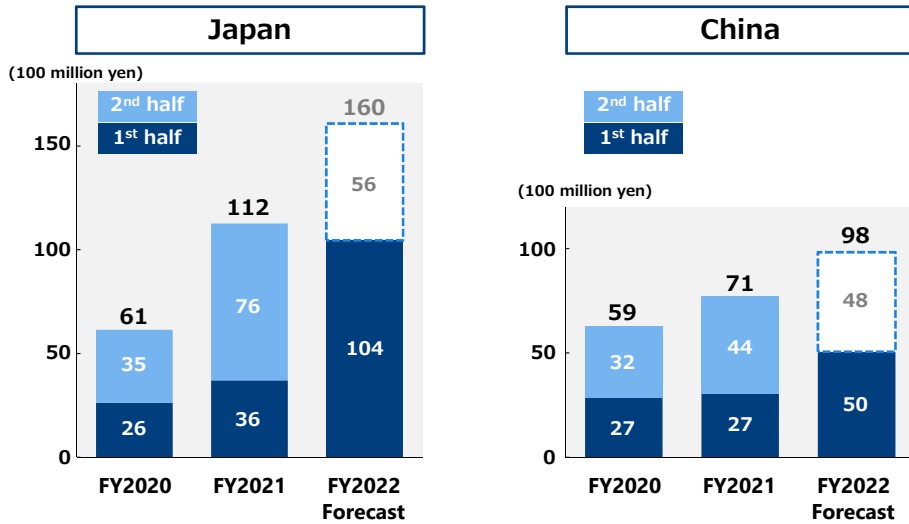
(millions yen)	FY2022 Full-year	Y/Y	Comparison with Aug. 3 forecast	
Net sales	59,300	+13,213 +28.7%	+5,100 +9.4%	Reagents Reagents for general research are recovering in earnest. Growth in the new Coronavirus PCR test-related product.
Reagents	46,375	+11,186 +31.8%	+5,781 +14.2%	Instruments Sales declined as demand for PCR instrument related to the new Coronavirus PCR test subsided.
Instruments	1,388	▲337 ▲19.6%	▲153 ▲9.9%	CDMO Increased in revenue for Regenerative Medicine, Gene Analysis and Testing, and Vaccine on CDMO
CDMO	11,388	+2,486 +27.9%	+41 +0.4%	Gene therapy Decrease in sales of investigational products
Gene therapy	146	▲121 ▲45.4%	▲569 ▲79.5%	Gross profit Increased due to higher sales and improvement in the profitability of CDMO
Gross profit	40,502	+8,630 +27.1%	+3,235 +8.7%	Operating profit Forecast 13 consecutive years of profit growth.
Operating profit	20,000	+6,047 +43.3	+3,000 +17.6%	

7 (NOTE) Explanation of year-on-year changes 

Full-year Forecast for FY2022: Sales for Reagents (1)



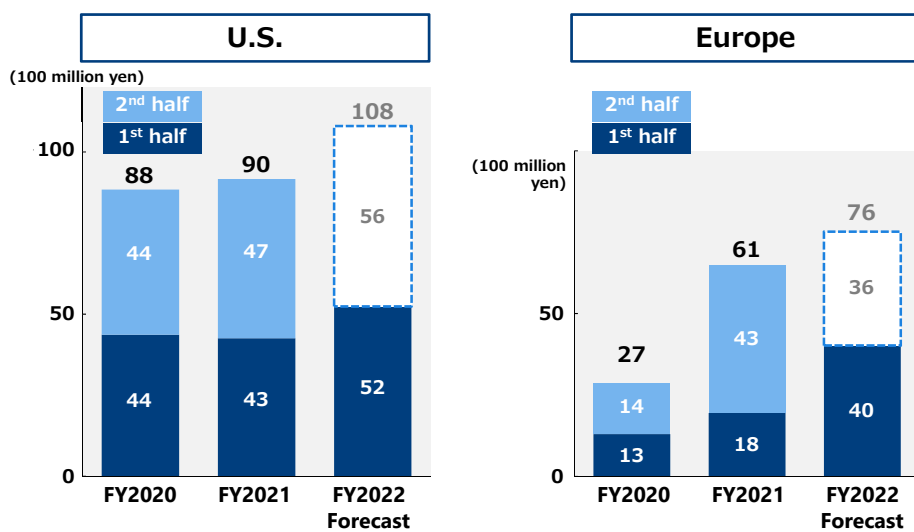
Full-year Forecast for FY2022: Sales for Reagents (2), by Region



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Full-year Forecast for FY2022: Sales for Reagent (3), by Region

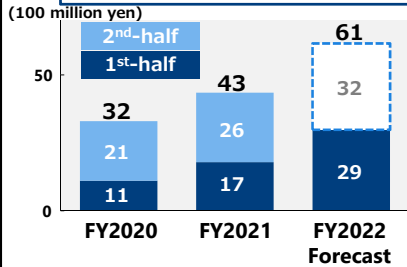


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Full-year Forecast for FY2022: CDMO

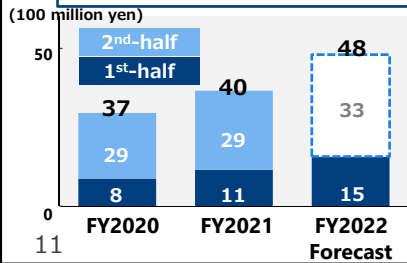
Net Sales of Regenerative Medicine



- Orders from pharmaceutical companies and bio-ventures for regenerative medicine product development projects are increasing.

- We have received orders for several COVID-19 vaccine projects. This contributes to the increase in revenue.

Net Sales of Gene Analysis and Testing

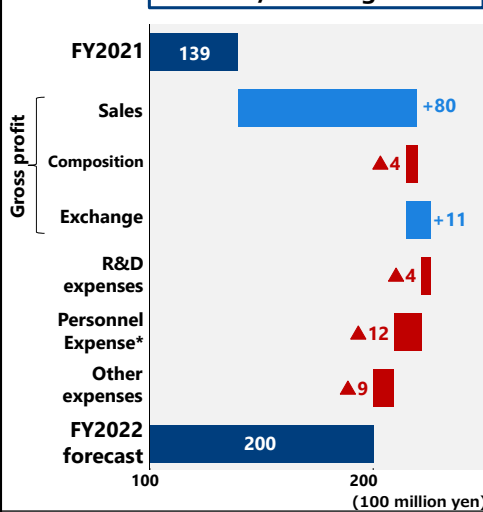


- We have achieved steady growth thanks to orders for several large-scale genome projects.

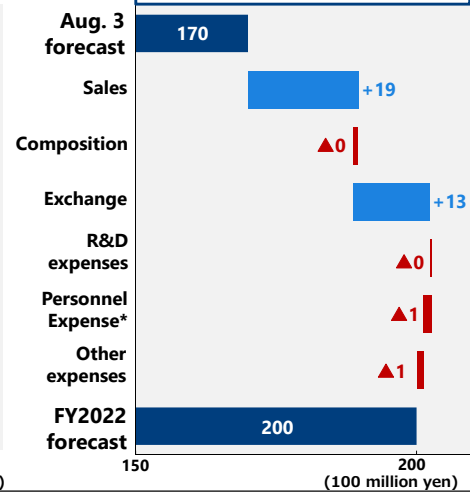
- In addition to academia, contracts for corporations' next-generation sequencer analysis have also grown.

Full-year Forecast for FY2022: Operating Profit

Y/Y Change



Comparison with Aug. 3 Forecast



12 * Excluding R&D personnel expenses



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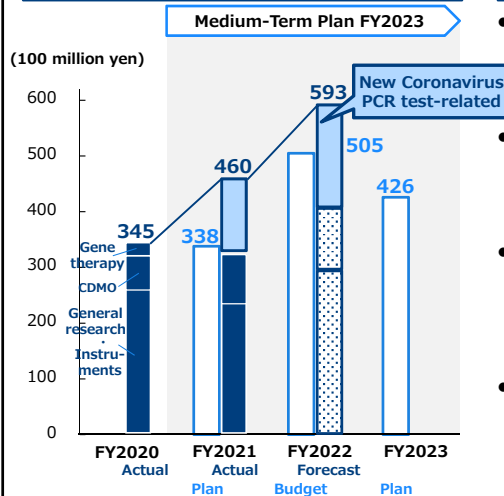
- Consolidated Quarterly Financial Results for FY2022 (for the Second Quarter Ended Sep. 30, 2021)
- Consolidated Financial Forecast for FY2022
- **Business Progress and Future Measures**

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Progress in Medium-Term Management Plan FY2023: (1) Consolidated Net Sales (Key Performance Indicator; KPI)

Sales trends and plan



Current status and direction

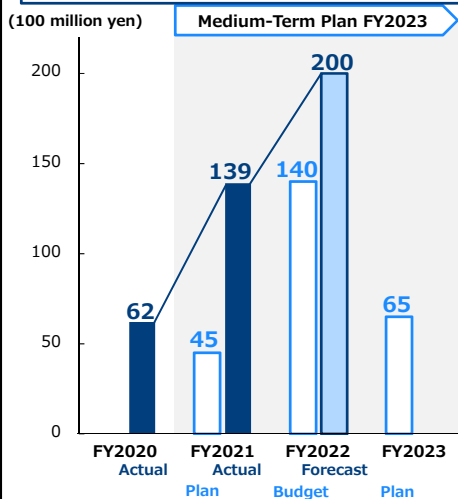
- In the fiscal year ended March 2021, sales of general reagents and instruments for general research declined, but total net sales then increased significantly due to our rapid response to demand for new coronavirus PCR testing reagents.
- The sales forecast for the fiscal year ending March 2022 is 59.3 billion yen, which is significantly higher than the target level for the final fiscal year (FY2023) of the Medium-Term Management Plan FY2023.
- Excluding the upside associated with increased demand for the new coronavirus PCR testing reagents, sales in the reagents for general research, instruments and CDMO business grew steadily, having reached the target level for the fiscal year ending March 2023.
- In the future, we will aim to continuously expand sales mainly in the reagent and CDMO business on the premise of a decrease in demand for the new coronavirus PCR testing reagents.

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Progress in Medium-Term Management Plan FY2023: (2) Consolidated Operating Profit (Key Goal Indicator; KGI)

Operating profit trends and plan



Current status and direction

- The fiscal year ended March 2021 started with a negative profit forecast that fully reflected the negative impact of the COVID-19 pandemic, but results were much better than expected.
- The forecast for the fiscal year ending March 2022 is 20 billion yen, which is significantly higher than the target level for the final fiscal year (FY2023) of the Medium-Term Management Plan FY2023.
- The target of 10 billion yen for the final year (FY2026) of the Long-Term Management Plan FY2026 has also been achieved.
- Keeping the direction of the Long-Term Management Plan FY2026 unchanged, we will make R&D investments ahead of schedule, and actively promote the development of basic drug discovery technologies.

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Utilizing our strength in PCR technology development, we continue to develop high-performance products and expand application fields

• Launch of "Takara Ex Premier DNA Polymerase", an enzyme for high-performance PCR (October 2021)

- It is a new flagship PCR enzyme for focusing on "Success," "Accuracy," and "Ease of Use" of experiments.

• Launch of PCR kit to detect coronavirus genes in sewage (October 2021)

- It has improved detection sensitivity and significantly reduced reaction time. Application to epidemiological studies and research is expected.
- Results of joint research with Professor Eiji Haramoto, Graduate School, Yamanashi University

• Launch of PCR kit to detect enteropathogenic bacterial genes (October 2021)

- It is for stool tests required by the Ministry of Health, Labour and Welfare for cooks.
- It simultaneously measures three species of enterohemorrhagic Escherichia coli, Salmonella spp., and Shigella spp., which cause food poisoning.
- Compared with conventional products, the operability is greatly improved and the inspection time is shortened.



• Launch of PCR kit for simultaneous diagnosis of swine fever and African swine fever (November 2021)


- It does not require a viral DNA/RNA extraction and purification process from samples, resulting in a significant reduction in time and labor compared with conventional methods.
- Results of joint research with the National Institute of Agricultural Sciences on the "Acceleration of ASF Vaccine Development through Public-Private Partnership and International Cooperation" included in the Ministry of Agriculture, Forestry and Fisheries' commissioned research project, "Comprehensive Regulatory Science Research Promotion Project for the Stable Supply of Safe Agricultural, Livestock and Fishery Products"

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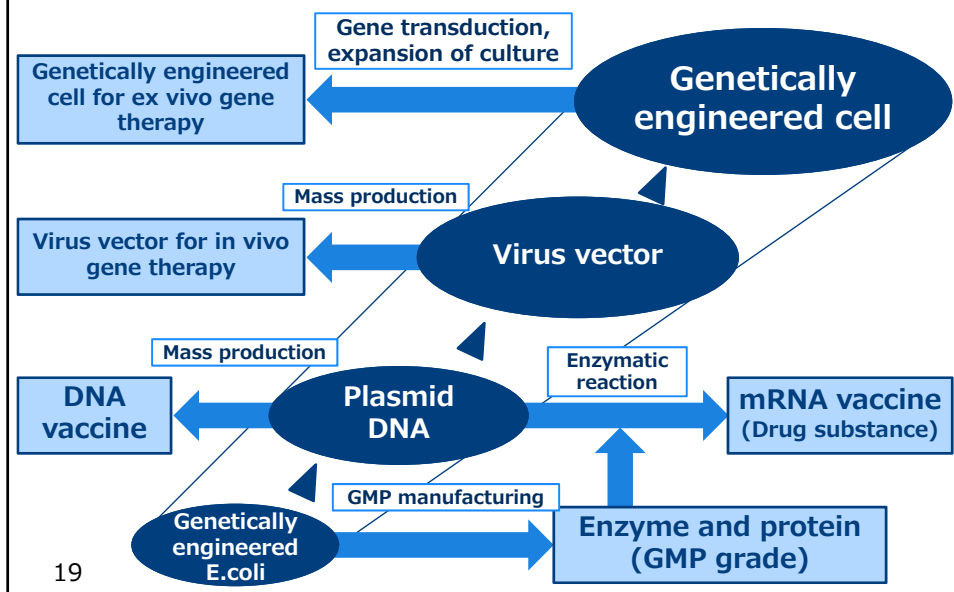


Steady Progress in Optimizing R&D and Production Systems New facilities in Japan and the United States begin operations

New domestic manufacturing facilities for in vitro diagnostics		New site of the U.S. subsidiary, Takara Bio USA	
Location	Head Office, Kusatsu, Shiga	Location	San Jose, California (10 minutes by car from San Jose International Airport)
Floor area	approx. 790 m ²	Land area	approx. 30,000 m ²
Mfg. capacity	8 million PCR reaction per month	Building area	approx. 12,000 m ² (6,000 m ² × 2 bldg.)
Scale of investment	Approx. ¥1 billion	Scale of investment	approx. ¥10 billion
<ul style="list-style-type: none"> They were selected by the Ministry of Economy, Trade and Industry to receive the "Project to Promote Domestic Investment for Supply Chain Measures." We have achieved a stable domestic supply of PCR testing reagents and reduced supply chain risks. 		<ul style="list-style-type: none"> We will further strengthen and expand product development functions for advanced research such as gene analysis and single-cell analysis using next-generation sequencers. We will further improve productivity by optimizing the Group's R&D system. We have newly deployed production functions for PCR enzymes in the United States. This enables agile product supply in response to local demand. 	
<div style="display: flex; justify-content: space-around;">   </div>			
<div style="display: flex; justify-content: space-around;"> 17 90 L fermenter Automated filling system </div>			

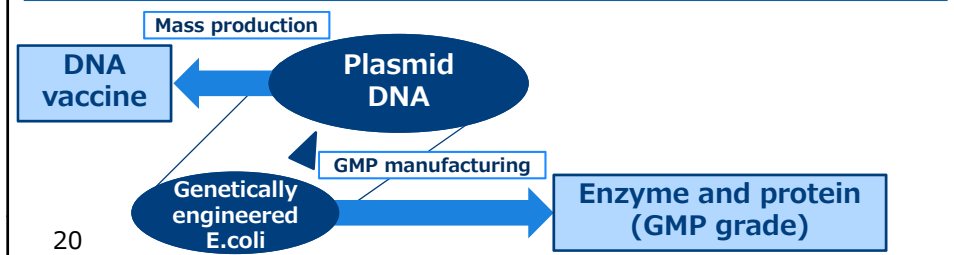
Partnership with Otsuka Pharmaceutical Co., Ltd. Agreement for TBI-1401 and TBI-1501 ends, while partnership continues for TBI-1301	
Items for which ended	
C-REV (TBI-1401)	<ul style="list-style-type: none"> License agreement for development and commercialization of an Oncolytic Virus, HF10 (Concluded December 15, 2016) Based on the results of phase I clinical trials for pancreatic cancer, we have considered the time required for future development.
CD19•CAR (TBI-1501)	<ul style="list-style-type: none"> License agreement for co-development and exclusive sales of CD19 CAR gene therapy product (Concluded April 9, 2018) We have considered an extension of the duration of phase I/II clinical trials for adult acute lymphoblastic leukemia and the approval of competing products.
Item for which joint	
NY-ESO-1•siTCR™ (TBI-1301)	<ul style="list-style-type: none"> We are developing a reliability assurance system required for applying for manufacture/marketing approval. We are building a post-marketing manufacturing system in the Company. Once the preparations are completed, Otsuka Pharmaceutical Co., Ltd. will submit an application for manufacture/marketing approval in Japan.
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CDMO Business (Regenerative Medicine): Utilizing Gene Therapy-Related Technologies to Deploy into Various Modalities

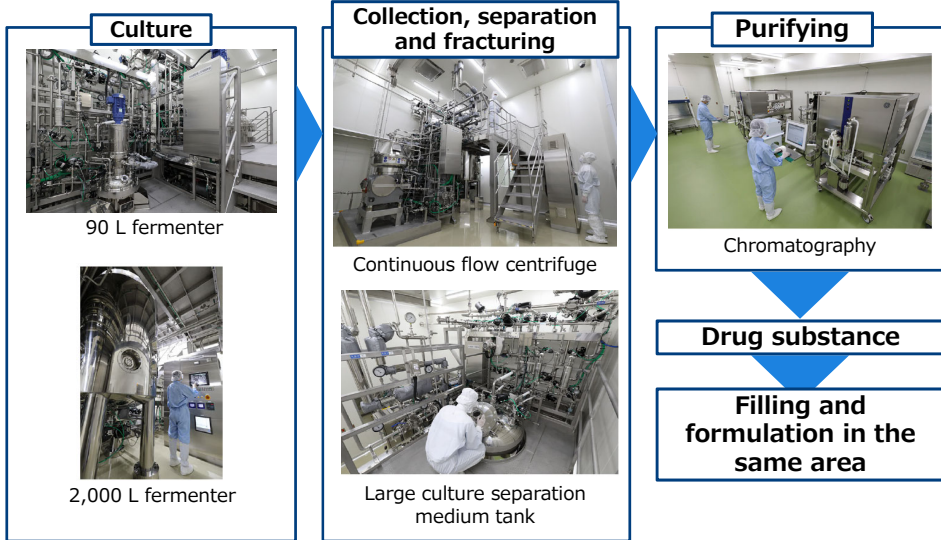


Production of Enzyme Protein/Plasmid DNA by Genetically Engineered *Escherichia Coli*

- We have enhanced production of GMP-grade proteins (enzymes for mRNA synthesis, such as RetroNectin®) by microbial culture.
- Plasmid DNA is used as a raw material for DNA vaccines, adeno-associated virus (AAV) vectors for gene therapy and mRNA vaccines.
- We have participated in the DNA vaccine development project for COVID-19 promoted by AnGes, Inc. We are developing a mass production system for plasmid DNA using subsidies from the Ministry of Health, Labour and Welfare's "Project for Emergency Development of Vaccine Production Systems."



Large manufacturing area of plasmid DNA under development in CGCP II



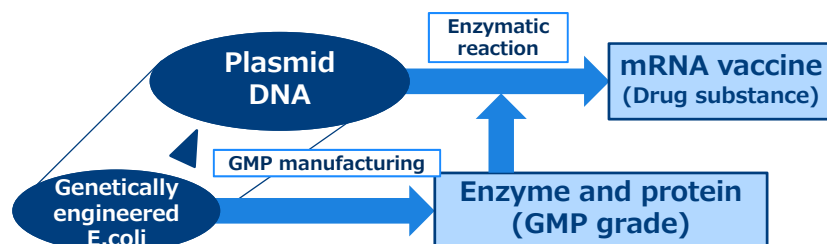
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mRNA vaccines are produced by enzymatic reactions using plasmid DNA as a raw material

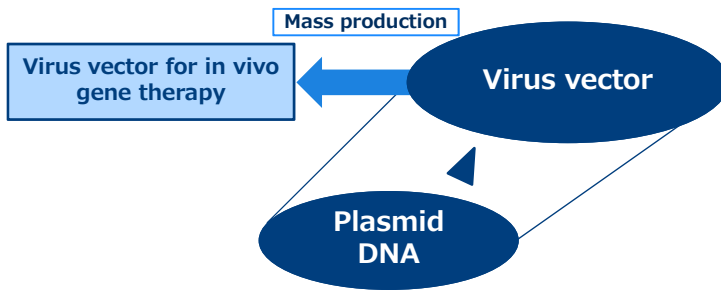
- We utilize GMP production technology and capacity for gene therapy vectors.
- We plan to produce raw materials and reagents such as plasmid DNA and mRNA synthetase. The development of a highly efficient manufacturing method with the functional improvement of enzymes is also under way.
- We have concluded an agreement with VLP Therapeutics Japan concerning contract manufacturing of replicon (next-generation mRNA) vaccine active pharmaceutical ingredients for the treatment of COVID-19.

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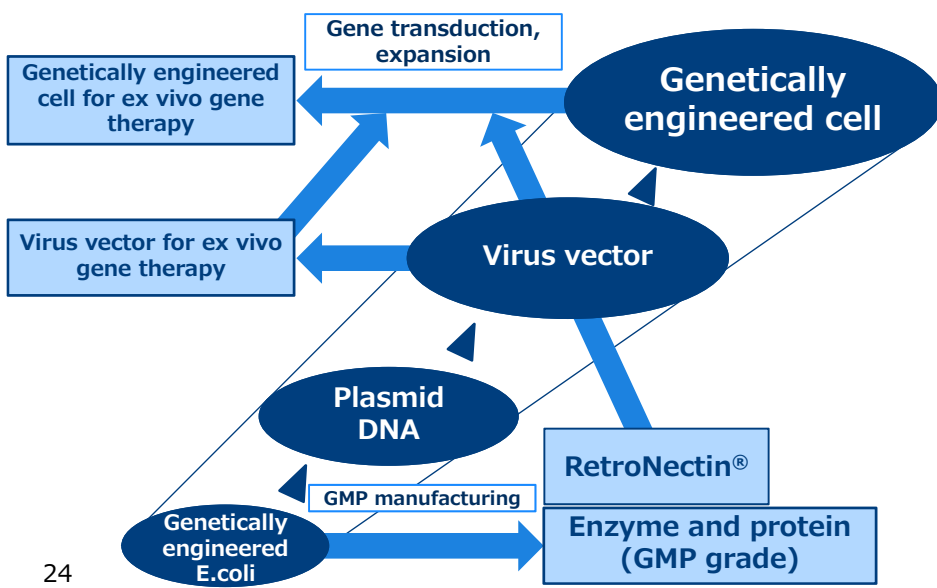
Production of viral vectors for gene therapy requires enhanced virus-producing cell lines and highly efficient purification techniques

- We focus on the development of mass production technologies for high-quality adeno-associated virus (AAV) vectors and lentiviral vectors.
- We also plan to accommodate large-scale production of AAV vectors for in vivo gene therapy in the 2,000 L class.



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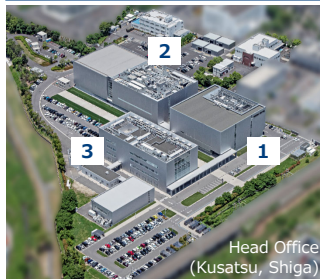
Focus on development of high-volume, high-efficiency manufacturing technologies for genetically engineered cell with a view to application to allogeneic cell



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Fully implement the CGCPs to become the driving force for expanding CDMO business

Main equipment and system



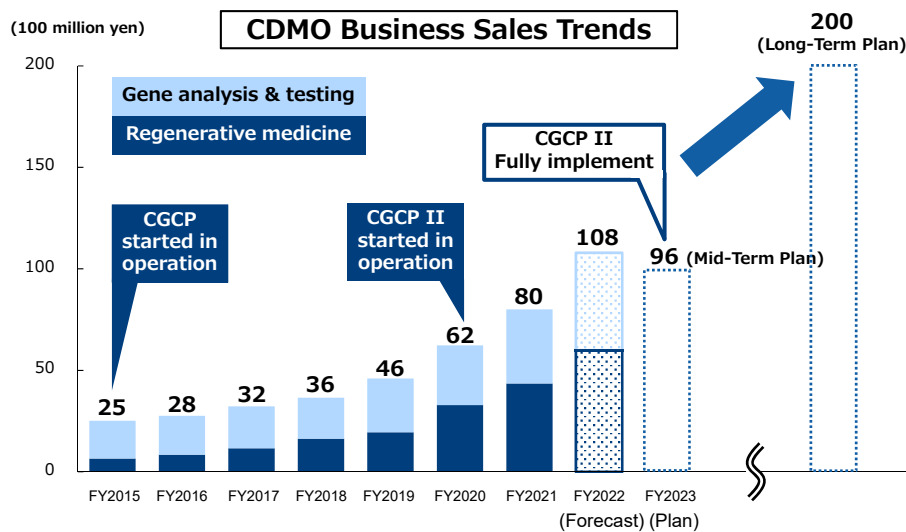
3 Main Building

Gene analysis and testing

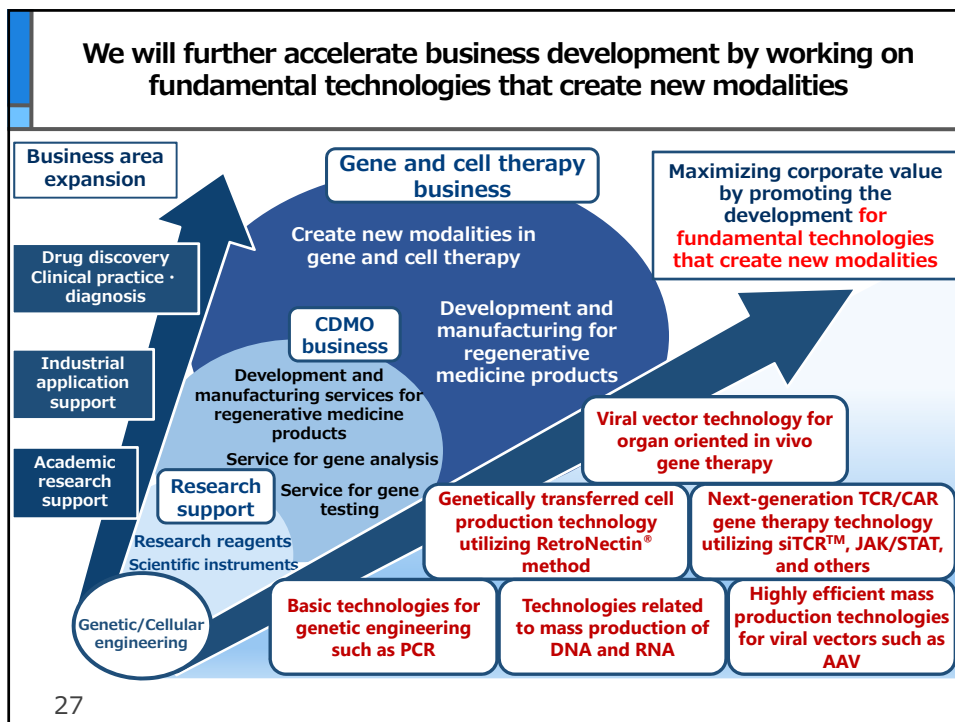
Approx. 1,200 m²
Various NGS for large- to small-scale analysis
Analyzable approx. 7,000 human genome/month

	1 CGCP Building 1 (CGCP)	2 CGCP Building 2 (CGCP II)
Plasmid DNA Proteins	<ul style="list-style-type: none"> Single-use bio reactor: 200 L x 3 Rocking type shaking bio reactor: 25 L x 2 	<ul style="list-style-type: none"> Fermenter (90 L & 2,000 L) x 2 [Scheduled start of operation in 2022]
Virus vector	<ul style="list-style-type: none"> Total of 6 suites Multi-chamber flask (up to 40) Rocking type shaking bio reactor: 25 L x 2 	<ul style="list-style-type: none"> Single-use bio reactor (fixed bed system) x 1 Rocking type shaking bio reactor: 25 L x 2 Single-use bio reactor 200 L x 1, 200 L & 2,000 L x 1 [Scheduled start of operation in 2022]
Cell	<ul style="list-style-type: none"> Total of 11 suites Biosafety cabinet x 31 CO₂ incubator x 40 Closed-system automatic culturing system 	<ul style="list-style-type: none"> Total of 3 suites [Scheduled start of operation in 2023]
Quality testing	—	Approx. 1,900 m ² Microbiology & virus testing, PCR testing, cell testing, etc.
Aseptic filling	Automated filling system (3,000 vials/day)	Automated filling system (20,000 vials/day)

Quantitative Targets of Medium-Term Plan FY2023 Already Achieved Aiming for CDMO business sales of ¥20 billion early




26 * Non-consolidated results (figures converted to current sales classifications) / expressed in forecasts. TAKARA



[Reference]

Reference Information (FY2022 Results)

- Consolidated Financial Results (2Q)
- Consolidated Financial Results (Full-year Forecast)
- Net Sales by Category (2Q)
- Net Sales by Category (Full-year Forecast)
- Reagents Sales by Region (2Q)
- Reagents Sales by Region (Full-year Forecast)
- Performance by Subsidiaries (2Q, Full-year Forecast)
- Exchange Rate (Actual, Forecast)

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[Reference]

Consolidated Financial Results (2Q)

(million yen)

	FY2022 2 nd -quarter	Y on Y		Comparison with Aug. 3 forecast	
		Change	Ratio	Change	Ratio
Net sales	31,551	+14,158	+81.4%	+1,851	+6.2%
Cost of sales	8,056	+2,490	+44.7%	▲693	▲7.9%
Gross profit	23,495	+11,667	+98.6%	+2,544	+12.1%
SG&A expenses	9,389	+1,298	+16.1%	▲160	▲1.7%
Operational profit	14,105	+10,368	+277.5%	+2,705	+23.7%
Ordinary profit	14,241	+10,421	+272.8%	+2,841	+24.9%
Net income attributable to owners of parent	10,009	+7,734	+340.1%	+2,109	+26.7%

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[Reference]

Consolidated Financial Results (Full-year Forecast)


(million yen)

	FY2022 Full-year	Y/Y		Comparison with Aug. 3 forecast	
		Change	Ratio	Change	Ratio
Net sales	59,300	+13,213	+28.7%	+5,100	+9.4%
Cost of sales	18,797	+4,582	+32.2%	+1,864	+11.0%
Gross profit	40,502	+8,630	+27.1%	+3,235	+8.7%
SG&A expenses	20,502	+2,583	+14.4%	+235	+1.2%
Operating profit	20,000	+6,047	+43.3%	+3,000	+17.6%
Ordinary profit	20,200	+6,040	+42.7%	+3,100	+18.1%
Net income attributable to owners of parent	14,100	+4,552	+47.7%	+2,200	+18.5%


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[Reference]					
Net Sales by Category (2Q)					
(million yen)					
	FY2022 2 nd -Quarter	Y/Y		Comparison with Aug. 3 forecast	
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Reagents	25,966	+12,629	+94.7%	+1,908	+7.9%
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Gene therapy	140	▲75	▲35%	+16	+13.4%
Total net sales	31,551	+14,158	+81.4%	+1,851	+6.2%

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[Reference]					
Net Sales by Category (Full-year Forecast)					
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	FY2022 Full-year	Y/Y		Comparison with Aug. 3 forecast	
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Reagents	46,375	+11,186	+31.8%	+5,781	+14.2%
Instruments	1,388	▲337	▲19.6%	▲153	▲9.9%
CDMO	11,388	+2,486	+27.9%	+41	+0.4%
Gene therapy	146	▲121	▲45.4%	▲569	▲79.5%
Total net sales	59,300	+13,213	+28.7%	+5,099	+9.4%

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[Reference]			
Reagents Sales by Region (2Q)			
(million yen)			
	FY2022 2 nd -quarter	Y/Y (Exchange excluded)	
		Chang	Ratio
Japan	10,452	+6,754	+182.7%
U.S.	5,202	+920	+21.4%
China	5,026	+1,864	+67.2%
Europe	4,041	+1,860	+100.4%
India	683	+456	+205.7%
Korea	559	+32	+6.6%
Total	25,966	+11,889	+89.1%

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[Reference]					
Reagents Sales by Region (Full-year Forecast)					
(million yen)					
	FY2022 Full-year	Y/Y (Exchange excluded)		Comparison with Aug. 3 forecast (Exchange excluded)	
		Change	Ratio	Change	Ratio
Japan	16,082	+4,824	+42.8%	+2,475	+18.2%
U.S.	10,815	+1,512	+16.7%	+88	+0.9%
China	9,840	+1,962	+27.6%	+940	+12.0%
Europe	7,601	+1,023	+16.7%	+157	+2.3%
Korea	1,082	+45	+4.6%	+6	+0.6%
India	953	+263	+40.4%	▲37	▲4.0%
Total	46,375	+9,631	+27.4%	+3,631	+8.9%

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[Reference]				
Performance by Subsidiaries (2Q, Full-year Forecast)				
(million yen)				
	2 nd -quarter Actual		Full-year Forecast	
	Net sales	Operating profit	Net sales	Operating profit
Takara Bio (Non-consolidated)	23,555	11,149	41,847	14,486
Takara Bio Europe (Consolidated)	4,203	825	8,041	1,459
Takara Biotechnology (Dalian)	2,537	785	4,539	1,214
Takara Biomedical Technology (Beijing)	5,368	979	10,463	1,627
Takara Korea Biomedical	604	100	1,180	186
DSS Takara India	691	122	971	144
Takara Bio USA	6,367	765	13,144	1,418

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[Reference]				
Exchange Rate (Actual, Forecast)				
(Unit: yen)	FY2021 2 nd -Quarter	FY2021 Full-year	FY2022 2 nd -Quarter	FY2022 Full-year
	Actual	Actual	Actual	Forecast
US dollar	108.25	106.77	107.82	109.10
Euro	119.34	121.88	129.88	129.60
Yuan	15.38	15.48	16.67	16.80
100 Won	8.97	9.06	9.64	9.60
Rupee	1.46	1.44	1.47	1.50
Sweden Krona	11.20	11.63	12.82	12.80
Pound	-	-	149.78	150.10

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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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