TaKaRa

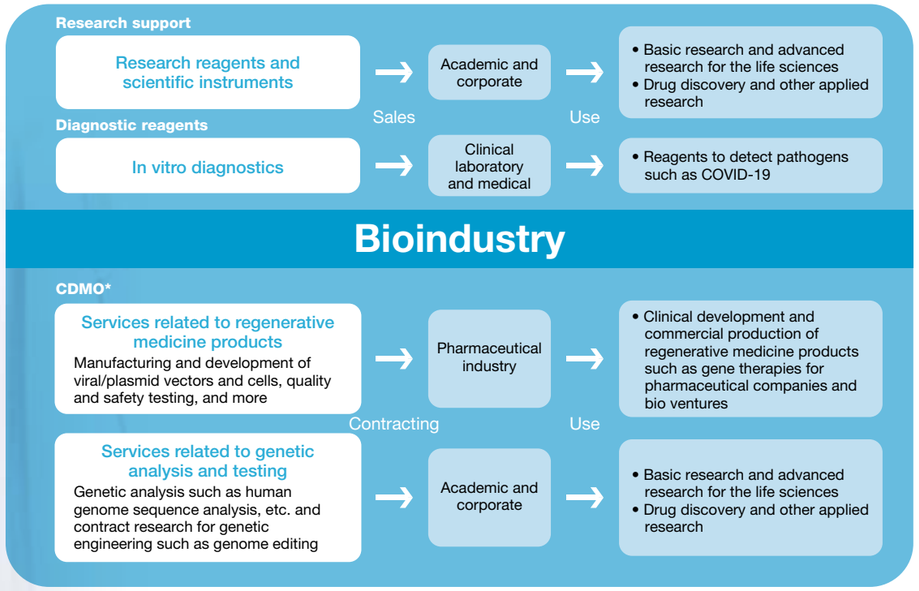
TAKARA BIO REPORT 2021

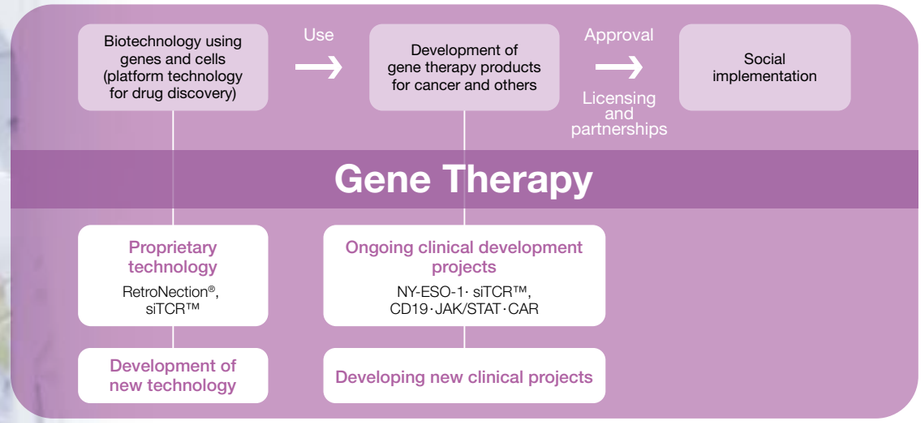
TAKARA BIO INC.

THE BIOTECHNOLOGY COMPANY™

Corporate Philosophy

Contributing to the health of humankind through the development of revolutionary biotechnologies such as gene therapy





*Here, CDMO (Contract Development and Manufacturing Organization) refers to provision of contract services for drug development and manufacturing, in all steps of the process from formulation to final manufacturing, for clients such as pharmaceutical companies. Takara Bio provides CDMO services focused on regenerative medicine products such as gene therapy.

Our History

Business

Bioindustry

1979
- Commenced sales of the first domestically produced restriction enzymes as reagents for genetic engineering research

1985
- Began DNA synthesis services

1988
- Acquired exclusive distribution rights in Japan for a gene amplification system using PCR technology

1990
- Began DNA sequence analysis services

1993
- Obtained worldwide, broad-ranging PCR-related patent licenses

1995
- Developed the RetroNectin® method for highly efficient retroviral transduction in hematopoietic stem cells

2000
- Launched full-scale genetic analysis services

2006
- Began next-generation sequence analysis services

2008
- Started Japan's first sponsor-initiated clinical trial of ex vivo gene therapy

2009
- Began iPS cell production services

2010
- Acquired C-REV project

2013
- Launched genome editing services

2014
- Completed construction of the Center for Gene and Cell Processing; began full-scale CDMO business providing manufacturing and development support services for regenerative medicine products

2015
- The Center for Gene and Cell Processing accredited as a foreign cell processor to conduct specific processed cell manufacturing

2016
- Obtained CAP-LAP certification for the contract genetic analysis business

2018
- Designated NY-ESO-1·siTCR™ as a product under the SAKIGAKE Designation System

2020
- Began selling Takara SARS-CoV-2 Direct PCR kit, an in vitro diagnostic

2020
- NY-ESO1·siTCR™ designated as an Orphan Regenerative Medicine

Gene Therapy

Company

1925
- **Established Takara Shuzo Co., Ltd. (now Takara Holdings Inc.)**

1993
- Established Takara Biotechnology (Dalian) Co., Ltd. in China

1995
- Established Takara Biomedical Europe S.A. (now Takara Bio Europe S.A.S.)
- Established Bohan Biomedical Inc. (now Takara Korea Biomedical Inc.)

2000
- Established DRAGON GENOMICS CO., LTD. (merged in 2002)

2002
- **Established Takara Bio Inc.**

Took over Takara Shuzo Co.'s biotechnology business and established Takara Bio Inc. in the city of Otsu, Shiga

2004
- Established Takara Biomedical Technology (Beijing) Co., Ltd.
- Listed on the TSE Mothers Index

2005
- Established Takara Bio USA Holdings Inc.
- Acquired U.S.-based Clontech Laboratories Inc. (now Takara Bio USA, Inc.)

2011
- Established DSS Takara Bio India Pvt. Ltd.

2014
- Acquired Cellectis AB (now Takara Bio Europe AB)

2015
- **Completed construction of new research facility in Kusatsu, Shiga; Headquarters functions relocated**

2016
- Changed listing to the First Section of the TSE

2017
- Acquired Rubicon Genomics, Inc. and WaferGen Bio-systems, Inc. (later merged into Takara Bio USA, Inc.)

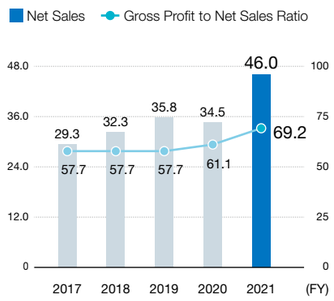
2020
- Launched the Center for Gene and Cell Processing II

2021
- Established Takara Bio UK Ltd.

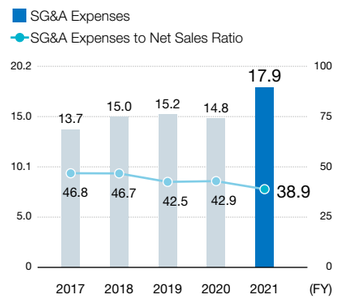
Financial Highlights

The company's accounting period is from April 1 until March 31 of the following year. This report refers to the period ending in March 2021 as FY2021. Other periods also use this denotation.

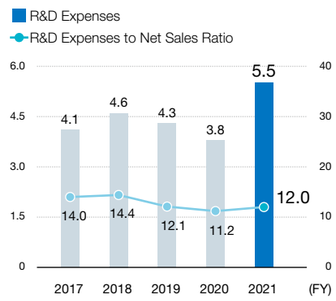
Net Sales (billion yen) / Gross Profit to Net Sales Ratio (%)



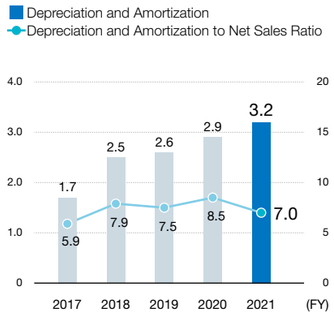
SG&A Expenses (billion yen) /SG&A Expenses to Net Sales Ratio (%)



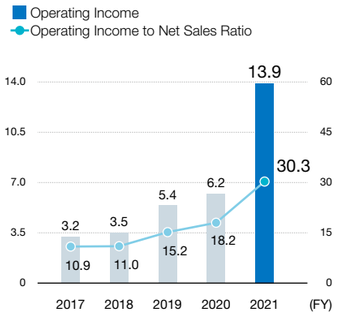
R&D Expenses (billion yen) / R&D Expenses to Net Sales Ratio (%)



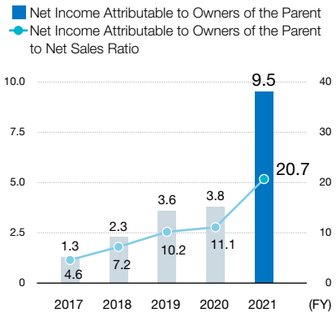
Depreciation and Amortization (billion yen) / Depreciation and Amortization to Net Sales Ratio (%)



Operating Income (billion yen) / Operating Income to Net Sales Ratio (%)

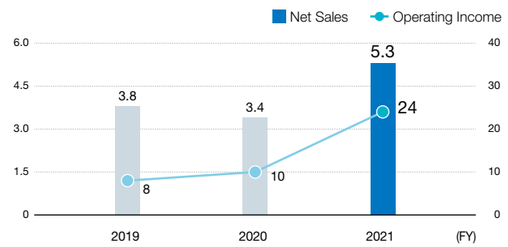


Net Income Attributable to Owners of the Parent (billion yen) /Net Income Attributable to Owners of the Parent to Net Sales Ratio (%)

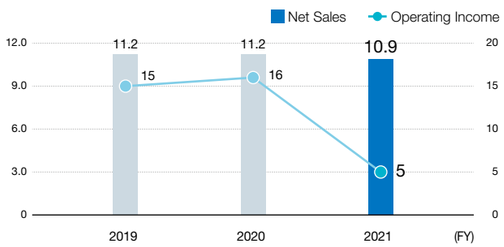


Financial Data of Major Subsidiaries Net Sales / Operating Income (billion yen)

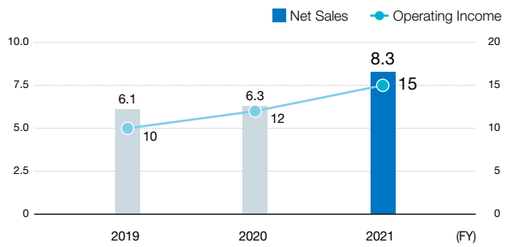
Takara Biotechnology (Dalian) Co., Ltd.



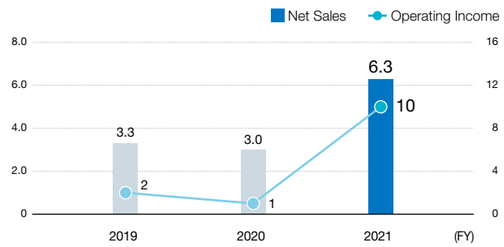
Takara Bio USA Inc.



Takara Biomedical Technology (Beijing) Co., Ltd.

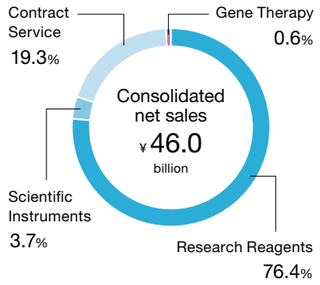


Takara Bio Europe S.A.S.*

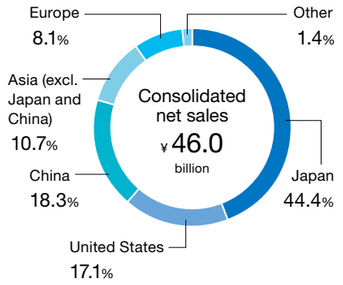


*Consolidated with Takara Bio Europe AB

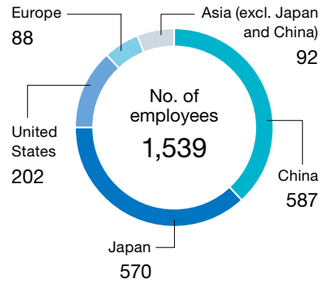
FY2021 Net Sales by Business Segment (%)



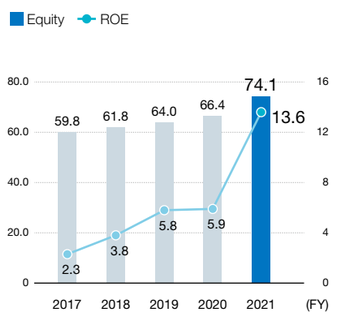
Net Sales by Region (%)



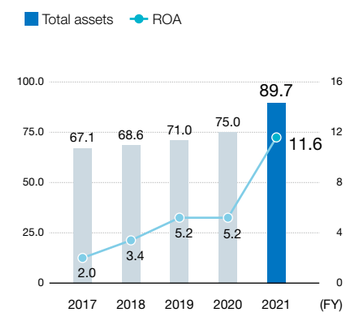
Employees by Region



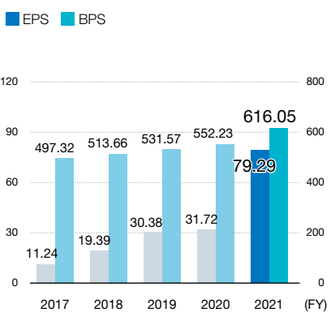
Equity (billion yen) /ROE (%)



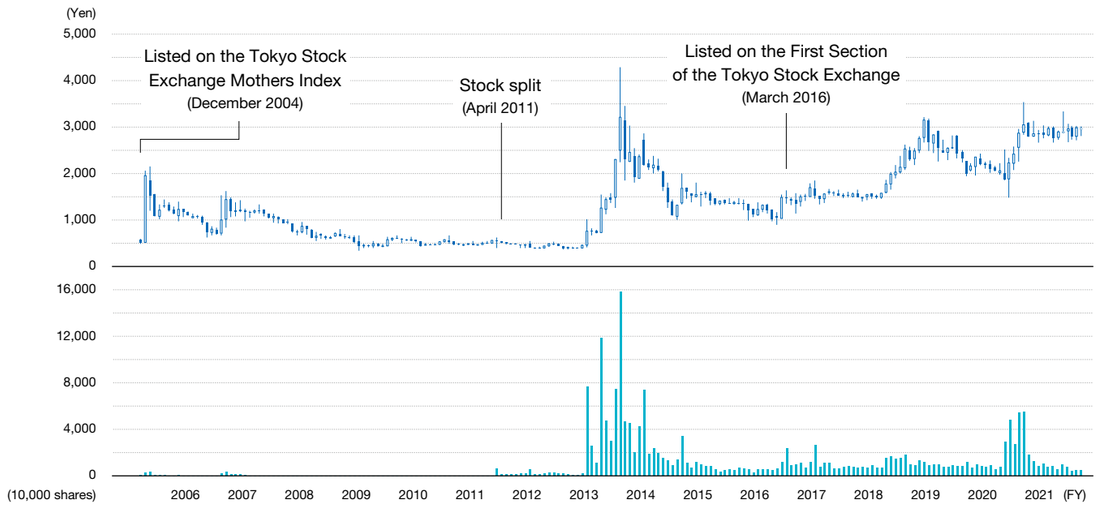
Total Net Assets (billion yen) /ROA (%)



EPS: net income per share (yen) / BPS: net assets per share (yen)



Share Values (above) and Turnover (below)



• Period: December 2004–June 2021
• Number of shares listed are those post-stock split adjustment

**Takara Bio aims to be a drug development company that continually creates new modalities by developing platform technology for drugs through our core businesses of research reagents/scientific instruments and CDMO services.
We will continue contributing to society by creating new value and achieving sustainable growth through proactive business activities.**

Koichi Nakao
President

FY2021 Business Performance

Increases in revenue and profit lead to record high performance

In fiscal 2021, our group worked toward becoming a drug development company that continually creates new modalities by developing platform technology for drug development through our research reagents/scientific instruments business and CDMO business, following our six-year Long-Term Management Plan 2026, which concludes in fiscal 2026, and our three-year Medium-Term Management Plan 2023, which concludes in fiscal 2023. We actively worked toward ensuring a stable supply of products related to COVID-19 PCR testing, and optimizing systems for manufacturing vaccines and other regenerative medicine products.

Our research reagents and scientific instruments business saw a large jump in net sales due to high demand for products related to COVID-19 PCR testing, to ¥46,086 million (133.3% of the previous year). The cost of sales was ¥14,214 million (105.6% of the previous year) due to a decrease in cost rate resulting from factors such as changes in sales composition and increased plant utilization, making gross profit ¥31,872 million (151.0% of the previous year). Selling and general administrative expenses were ¥17,919 million (120.8% of the previous year) due to an increase in R&D and other expenses, and operating income increased to ¥13,952 million (222.4% of the previous year).

Following growth in operating income, ordinary income increased to ¥14,159 million (223.1% of the previous year), and net income attributable to owners of the parent to ¥9,547 million (249.9% of the previous year). We achieved record high performance not only in terms of net sales, but also in all other profit-related figures, and our operating income has increased for 12 consecutive periods.

Research Reagents

Takara Bio offers a wide variety of products and services from basic research to industrial applications in the life sciences to universities and companies all over the world.

In our research reagents business, revenue from regular research reagents decreased due to a pandemic-related slump in research across the life sciences field. However, due to greatly increased sales of products related to COVID-19 PCR testing, overall revenue from research reagents increased to ¥35,189 million (141.7% of the previous year). Note that net sales figures for research reagents also include sales of in vitro diagnostics, which we began selling in Japan in November 2020.

Scientific Instruments

Revenue from scientific instruments increased due to greater sales of PCR machines for COVID-19 PCR testing, with net sales at ¥1,726 million (139.0% of the previous year).

Contract Service

Performance of contract services for regenerative medicine products remained robust due to increasing activity in development of regenerative medicine products such as gene therapy at pharmaceutical companies. In this period, we also added contract services related to COVID-19 vaccines.

Revenue from contract services related to gene analysis and testing grew due to various factors, including being contracted to conduct a large whole genome sequencing project.

Consequently, this period's net sales greatly increased to ¥8,910 million (143.9% of the previous year).

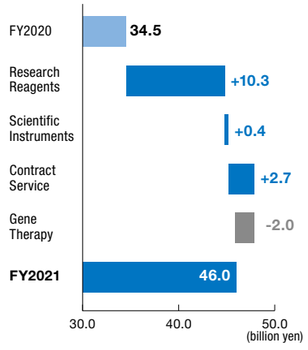
Gene Therapy

Due to factors such as reduced royalties from pharmaceutical companies, our gene therapy business saw revenue decrease by ¥2,027 million from the previous year, to ¥268 million (11.7% of the previous year).

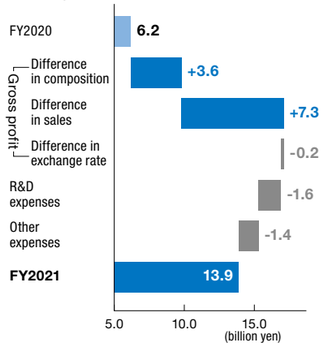
FY2021 business performance

		YoY
Net Sales	46.0 billion	133% ↗
Operating Income	13.9 billion	222% ↗
Net Income Attributable to Owners of the Parent	9.5 billion	250% ↗
ROE	13.6%	7.7 points ↗

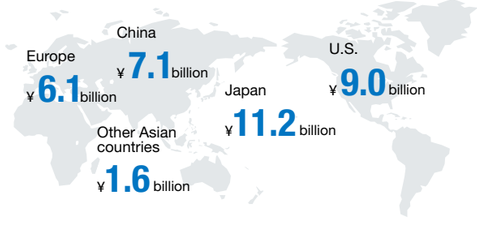
Changes in sales by category



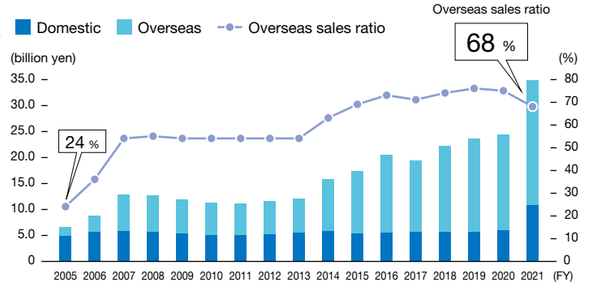
Changes in operating income composition



Research reagent* sales by region



Changes in research reagent* sales and overseas sales ratio



*All include in vitro diagnostics

Shareholder Return

Considering the management performance and financial condition overall, Takara Bio recognizes a basic policy aimed at profit contribution, positioning the profit distribution to shareholders as an important issue for management as well as enhancing the internal reserves to strengthen R&D activities.

In accordance with this policy, Takara Bio paid year-end dividends of ¥16 per share, an ¥8 increase over the ¥8 per share dividend the previous year. We have now increased dividends for nine consecutive terms.

Outlook for FY2022 Business Performance (released August 3, 2021)

We anticipate that revenue from sales will increase with growth in sales of COVID-19 PCR testing reagents, recovery of the general market for research reagents from its pandemic slump, as well as growth in contract services and gene therapy. We also anticipate an increase in gross profit due to increased revenue and reduced cost rate. Selling and general administrative expenses will increase because we plan to actively increase R&D and personnel spending.

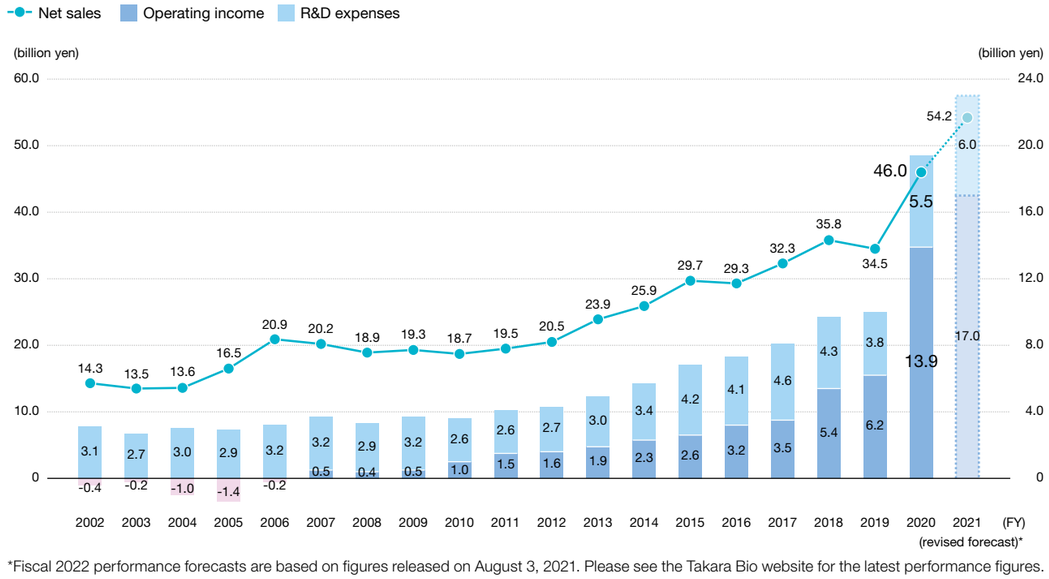
Consequently, we predict that in fiscal 2022 sales will increase to ¥54,200 million (117.6% of the previous year), gross profit to ¥37,267 million (116.9% of the previous year), operating income to ¥17,000 million (121.8% of the previous year), ordinary income to ¥17,100 million (120.8% of the previous year), and net income attributable to owners of the parent to ¥11,900 million (124.6% of the previous year).

These forecasts assume that the effects of the pandemic will persist for some time into fiscal 2022, and consequently may vary depending on future circumstances. If our performance forecasts need to be revised, we will promptly publish that information.*

Progress toward Medium-Term Management Plan 2023 and Long-Term Management Plan 2026

In May 2020, we created our Medium-Term Management Plan 2023 and Long-Term Management Plan 2026, and defined quantitative targets, management indicators, and business strategies. However, income was much better than expected in fiscal 2021 due to the success of our COVID-19 PCR testing-related products, and thus we achieved the target figures for the final fiscal year of the plans early. Nevertheless, I believe we have yet to finish the work of building the growth foundation we set forth in our medium- and long-term plans. Therefore, we will leave the quantitative targets, indicators, and business strategies in those plans as they are, and continue to actively invest in R&D and equipment to expand our business.

Performance since founding (net sales, operating income, and R&D expenses)



*Fiscal 2022 performance forecasts are based on figures released on August 3, 2021. Please see the Takara Bio website for the latest performance figures.

R&D, Capital Investments, and Strengthening Our Business Base

In the area of R&D, we are strengthening our system for developing new products for our reagents business, which serves as both a technological and revenue base for our company. Therefore, we are working to maximize synergy across R&D systems in our three key regions of Japan, the U.S., and China, and urgently working to bring new products to market while implementing strategies such as open innovation. In our scientific instruments business, we are tackling the challenge of developing new systems by combining our instruments with our proprietary reagents. In our CDMO business, we are putting effort into developing peripheral technology for next-generation sequencing (NGS) that can be used to develop platform technology for regenerative medicine products or for clinical diagnosis. In our gene therapy business, we are cultivating new clinical projects not only through in-house development, but also by developing drug candidates identified by academic researchers.

In the area of capital investments, we are restructuring our manufacturing capabilities. Research reagent manufacturing has been concentrated at our plant in Dalian, China, but in light of recent changes in global conditions and effects of the pandemic, we are aiming to increase efficiency and competitiveness while reducing supply chain risk. In Japan, we are adding facilities for manufacturing critical components of PCR test reagents and assay kits, such as in vitro diagnostics, at our headquarters in Kusatsu, Shiga Prefecture. We are also expanding Japanese facilities for our CDMO business, including vaccine manufacturing services. In the U.S., we decided to add capability to manufacture PCR enzymes and other products to our new hub in San Jose, California where we are gearing up to launch manufacturing operations around the fall of 2021. In Europe, we are building manufacturing systems for cell and culture medium products at our manufacturing hub in Gothenburg, Sweden.

To strengthen our business base, we are actively working to build up personnel, an organizational structure, and a work environment that will support long-term business expansion, as well as working on management challenges such as maximizing shareholder return and increasing ROE.

Promoting Sustainability Management

Guided by our corporate philosophy to “contribute to the health of humankind through the development of revolutionary biotechnologies such as gene therapy,” and from the perspective of increasing our medium- to long-term corporate value, we are working to solve various social challenges concerning sustainability, in health as well as other areas, through our business activities.

This year, we launched a Sustainability Promotion Committee chaired by the President, identified important issues we call “materialities,” and defined specific goals for each materiality, and have been taking action to achieve those goals. Going forward, we will continue to formalize our efforts to implement sustainability management, with the aim of striking a balance between becoming a sustainable company and achieving sustained growth of Takara Bio Group.

Quantitative targets in our medium- and long-term management plans and progress toward those targets

		Medium-Term Management Plan 2023 (FY2023)	Long-Term Management Plan 2026 (FY2026)	FY2021 (Result)	FY2022 (Forecast)
Quantitative targets	Operating income	6.5 billion	10.0 billion	**13.9 billion**	**14.0 billion**
	ROE	6% or more	8% or more	**13.6%**	**12.6%**
KPI*	Net sales	42.6 billion	50.0 billion	**46.0 billion**	**50.5 billion**
	R&D expenses	6.3 billion	7.0 billion	**5.5 billion**	**5.8 billion**

*KPI: key performance indicator

Point 1

Actively invest in R&D and equipment. Further expand our reagent and CDMO businesses, with the aim of sustained growth.

Point 2

Put effort toward building a foundation for increasing business performance in the long term through strategies such as personnel training, and speed up business development toward becoming a “drug development company.”

Point 3

Keep sustainability management in mind and leverage biotechnology to strike a balance between becoming a sustainable company and achieving sustained growth of Takara Bio Group.

Business strategy 1 Business Efforts Related to COVID-19

We are engaging in efforts such as building a rapid and simple PCR testing system for COVID-19, contributing to molecular epidemiological research, and collaborating in vaccine development.

Building a rapid and simple PCR testing system

We successfully developed a SARS-CoV-2 Direct Detection RT-qPCR Kit, a direct test kit that does not require RNA extraction and purification from the specimen, and began selling this kit in May 2020. With this kit, the tasks of extracting and purifying RNA from the specimen, which used to take about two hours, can be replaced with a quick ten-minute pretreatment. In addition, the test gives results in about one hour because it uses Takara Bio's proprietary rapid PCR technique. Moreover, whereas nasopharyngeal swabbing is complicated to perform and poses a high risk of infection, this test uses saliva samples instead, thus enabling simple and rapid PCR testing (Fig. 1).

In November, we also began selling Takara SARS-CoV-2 Direct PCR kit, an approved in vitro diagnostic. Now Takara Bio products are meeting an even wider range of testing needs.

Takara Bio is working to ensure a stable supply of these PCR-related products. We have been equipping the facilities at our headquarters in Kusatsu, Shiga Prefecture for manufacturing these products, and plan to start operations in fall 2021.

Collaboration in vaccine development

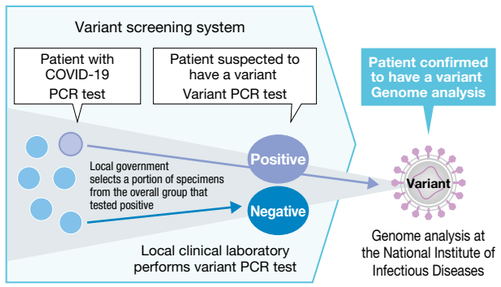
We are leveraging our experience in clinical development of gene therapy and CDMO services for regenerative medicine products to collaborate in several vaccine development projects.

Contributing to molecular epidemiological research

As foreign variants of the coronavirus have also been detected in Japan, the variant surveillance system is being intensified (Fig. 2).

Takara Bio is developing and selling rapid and simple PCR kits to detect genetic variants for use as research reagents. To ensure that new variants can be responded to quickly, we have created a system for developing and commercializing reagents to detect those mutations and then mass producing those reagents, all within about three weeks. We are also contributing to molecular epidemiological research by conducting whole genome sequencing of the coronavirus using next-generation sequencers.

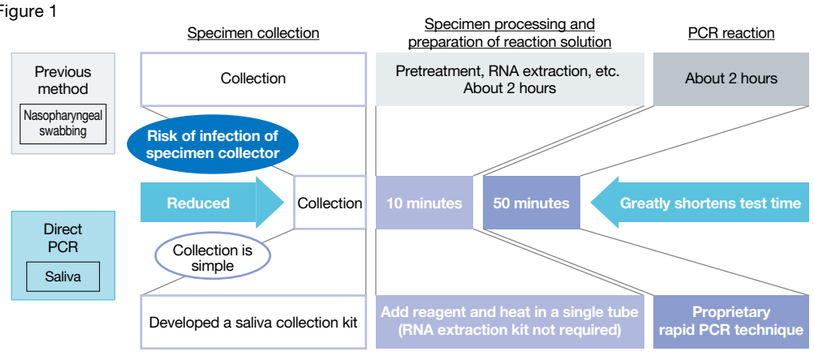
Figure 2



*In areas where a variant is confirmed, the percentage of specimens tested is increased and screening is intensified

Source: Adapted from documents from the Ministry of Health, Labour and Welfare Advisory Board for COVID-19 Measures

Figure 1



Thermal Cycler Dice® Real Time System Ⅲ

SARS-CoV-2 Direct Detection RT-qPCR Kit

Business strategy 2 Improving and Restructuring Manufacturing Hubs to Boost Productivity

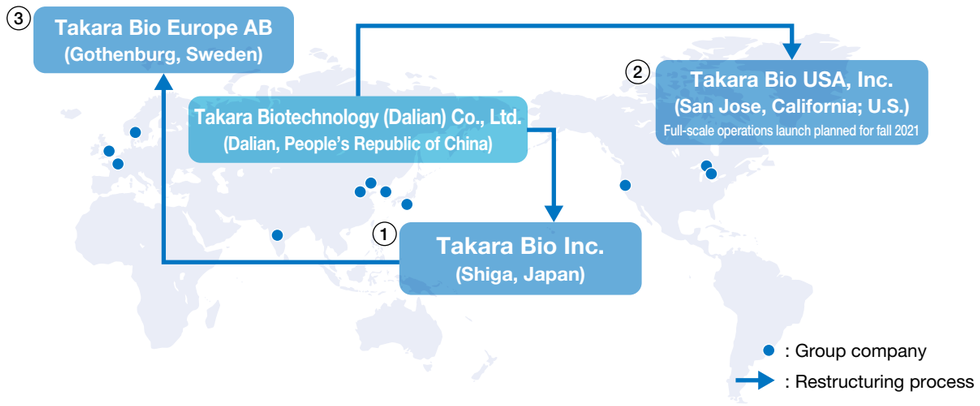
Research reagent manufacturing has been concentrated at Takara Biotechnology in Dalian, China, but considering various factors such as recent changes in global conditions and effects of the pandemic, we are aiming to increase productivity and disperse risk by improving and restructuring our manufacturing hubs.

To strengthen our stable supply system within Japan, we are developing our manufacturing system for PCR test reagents such as in vitro diagnostics for COVID-19 testing, with assistance from government subsidies*.

At Takara Bio USA, Inc. we will expand R&D capabilities and add capability to manufacture PCR enzymes to our new hub in San Jose, California where we are planning to launch full-scale operations in the fall of 2021. This will create a system that will allow us to flexibly and nimbly respond to demand in the U.S.

At Takara Bio Europe AB in Gothenburg, Sweden, we are effectively utilizing staff specialized in cell culture technology to strengthen our manufacturing systems for cell and culture medium products, including cellular therapeutics such as ES cells.

In this way, we intend to increase efficiency and are increasing productivity across the entire Group by restructuring our manufacturing systems across Japan, the U.S., China, and Europe.



FY2022 Capital Investment Plan

① Japan (Kusatsu)

- Improvements to facilities for manufacturing PCR reagents such as in vitro diagnostics*
- Vector manufacturing equipment, cell processing room for producing transduced cells, expansion of GMP/GCTP** systems*

② U.S. (San Jose)

- Improvements to manufacturing equipment, including addition of equipment to produce PCR enzymes
- Expansion of R&D capabilities

③ Europe (Gothenburg)

- Strengthening of manufacturing systems for cell and culture medium products, including cellular therapeutics such as ES cells

*Ministry of Economy, Trade and Industry Program for Promoting Investment in Japan to Strengthen Supply Chains
Ministry of Health, Labour and Welfare Urgent Improvement Project for Vaccine Manufacturing Systems
**GMP: Standard for manufacturing control and quality control for pharmaceutical products
GCTP: Standard for manufacturing control and quality control for regenerative medicine products

Bioindustry Business

Takara Bio supports academic and corporate life sciences activities by offering reagents, instruments, and CDMO services.

Reagents and Instruments

Takara Bio sells research reagents and scientific instruments under three unique brands: TaKaRa®, Clontech®, and Cellartis®. These brands meet a wide range of needs in the life sciences field throughout the world, from basic and cutting-edge research to industrial applications.

Products under the TaKaRa® brand are developed and sold by Takara Bio, and the brand offers an extensive lineup that covers all fields of bio research, including genetic, protein, and cellular engineering. It got its start as the first brand in Japan to develop and market restriction enzymes, back in 1979. PCR systems (machines and reagents) were soon added to the product lineup as well. Over its more than 40 years of history, TaKaRa® has added more and more products, and provides powerful support to bio researchers. In 2020, we added in vitro diagnostics using PCR technology, further expanding our scope.

Our Clontech® brand was developed by the former Clontech Laboratories (now Takara Bio USA, Inc.) and primarily offers products for advanced molecular biological research. It has particularly strong product offerings for functional genomic analysis, protein interaction research, and DNA library construction. We are developing outstanding products for the rapidly expanding market of next-generation sequencers under this brand. In the area of scientific instruments, we are developing and marketing an ultralow input genetic analysis system for single-cell analysis.

Our Cellartis® brand is developed by a company formerly called Cellartis AB (now Takara Bio Europe AB) founded by members of the University of Gothenburg in Sweden. Its product lineup includes cell products such as ES and iPS cells, as well as products for advanced stem cell research such as products for cell culturing.

TaKaRa

Offers a wide range of products for genetic engineering and all other kinds of biotechnology research applications.

Main products
- Genetic research reagents
- Genetic testing kits
- Genome analysis services
- Products related to novel coronavirus testing (including in vitro diagnostics)

Clontech

Has a lineup of products optimized for advanced research in fields such as molecular and cell biology.

Main products
- Analytical reagents for next-generation sequencers
- Single-cell analysis systems
- Gene expression research reagents
- Fluorescent proteins series for gene function analysis
- Genome-editing research reagents

cellartis

Offers iPS cell products and other products used in stem cell research, as well as contract services in the field.

Main products
- iPS cell research reagents
- Products for stem cell culturing and induction of differentiation

CDMO services

Through our CDMO (Contract Development and Manufacturing Organization) business, Takara Bio provides contract services for drug development and manufacturing, in all steps of the process from formulation to final manufacturing, for clients such as pharmaceutical companies. Our two top fields of focus are services related to regenerative medicine products such as gene therapy, and services related to genetic analysis and testing, such as genome sequencing and genetic analysis for regenerative medicine products.

At our Center for Gene and Cell Processing, which is the hub for our CDMO business, we are enhancing our capabilities for manufacturing and quality control testing for vectors and transduced cells. As we expand our facilities, we are urgently working to meet the growing demands from CDMO services by developing efficient expansion culture methods and technology to scale up vector production, as well as by automating manufacturing processes.

Contract Services Related to Regenerative Medicine Products

We provide various contract services in the area of regenerative medicine products.

Main services
- Manufacturing of viral vectors
- Manufacturing of gene-transduced cells
- Quality and safety testing
- Cell banking

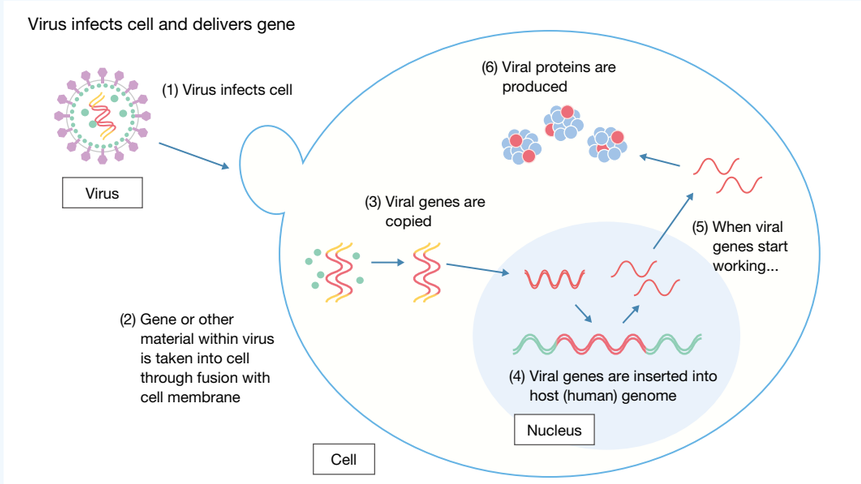
Contract Services Related to Genetic Analysis and Testing

We provide contract services for advanced genetic analysis and testing using the latest technology and devices.

Main services
- Sequencing (e.g., of the full human genome)
- Comprehensive analysis of cancer-related genes
- Intestinal flora analysis
- Cell line creation through genome editing

TOPICS Viral vector technology needed for gene transduction

The ability of viruses to infect cells can be exploited to have viruses become gene transporters and transduce a gene of interest into cells. Viruses that have been made non-pathogenic and have been modified for improved gene transduction are called viral vectors. Viral vectors play a central role in gene therapy, and have a major effect on outcomes such as treatment effectiveness. Takara Bio has been developing viral vector technology for a long time, and we are using this technology in applications such as our own products, CDMO services, and gene therapy projects.



Gene Therapy Business

We are developing platform technology for drug development to maximize the value of projects out-licensed to pharmaceutical companies and develop new clinical projects that seek to solve current issues with gene therapy.

Out-licensed projects

In close collaboration with our business partners, we structure systems for manufacturing and supply of regenerative medicine products with an eye to bringing them to market, and also work on expanding indications of approved products.

New clinical development projects

We are planning to start clinical trials of our new CAR gene therapy, which is currently being investigated in preclinical trials, in fiscal 2023.

Developing platform technology for drug development

We are putting effort into developing platform technology for drug development in areas such as gene therapy.

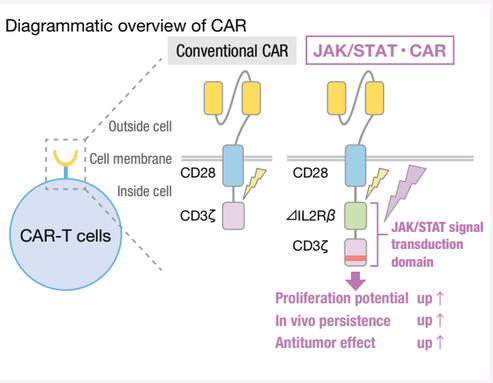
- Establish methods for mass production of viral vectors such as AAVs
- Develop next-generation CAR gene therapy for solid cancers
- Develop viral vectors for new organ-specific in vivo gene therapies
- Develop next-generation TCR/CAR gene therapy with a persistent antitumor effect

TOPICS Next-generation CAR gene therapy technology: JAK/STAT・CAR

CAR gene therapy is dramatically effective against blood cancers, has been approved by regulatory authorities, and is currently used in practice. However, relapse is an issue.

Relapse has been attributed to two phenomena that have been observed: (1) that CAR-T cells produced by transduction of T-cells (a type of immune cell) with the CAR gene do not persist in the patient's body, and (2) that cancerous blood cells stop expressing the antigens that serve as targets for immune cells to attack them.

In next-generation CAR therapy, T-cells are transduced with a gene that gives them the ability to activate the JAK/STAT signaling pathway, which is involved in long-term T-cell survival. This increases the proliferative potential and lifespan of T cells compared with conventional CAR therapy, and has been shown to product a superior antitumor effect (Kagoya Y, et al. Nat Med. 2018 24(3): 352-359).



We are aiming for technological development and social implementation of gene therapy

Junichi Mineno, Director & COO

Takara Bio has been developing gene therapies for a long time, and our current projects include engineered T cell therapy and an oncolytic virus. We are also leveraging our experience in developing these products to actively expand our CDMO business, where we support development and manufacturing of regenerative medicine products such as vaccines and gene therapies. These treatments we are developing are new modalities that use genes and cells as drugs, and show promise for treating and improving patient QOL for diseases for which sufficiently effective treatments have not yet been established. However, this is a still-developing field, and many issues remain to be solved.

In our sustainability activities, we name "health" as one of the materialities (important issues), and going forward, we plan to continue solving many issues that exist with gene therapy, and actively pursue technological development, capital investment, and education of specialized personnel to achieve social implementation and address these difficult challenges.

We are conducting corporate governance to achieve corporate social responsibility

Yoh Hamaoka, Director & CFO

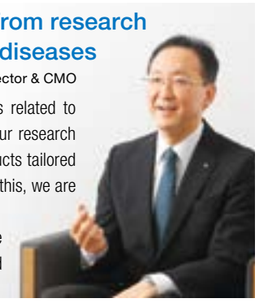
I believe that we need to work to collaborate appropriately with stakeholders and establish a strong corporate governance system to achieve sustainable growth and increase our medium- to long-term corporate value, with Takara Bio's corporate philosophy as our guide.

Our compliance activities consist of implementation system optimization, employee education, proper employment of internal communication channels, risk management (everyday risk management), and crisis management (risk management in times of emergency).

We see protecting the rights of minority shareholders as particularly important considering that Takara Bio is a publicly listed parent/subsidiary pair with Takara Holdings. We will strive to maintain and achieve fairness and transparency based on internal regulations in our dealings with Takara Holdings and other group companies, and are working to build a governance system.

We will develop need-oriented products and ensure their stable supply, from research products for the life sciences to test reagents for diagnosis of infectious diseases

Tsuyoshi Miyamura, Director & CMO



In fiscal 2021, we prioritized rapid development, manufacturing system optimization, and stable supply for products related to COVID-19 PCR testing. We are putting effort toward using the genetic engineering technology we cultivated through our research reagents business as a platform to develop products that test for viruses that cause infectious diseases, as well as products tailored to regional characteristics. At the same time, we are working to ensure a stable supply of these products. To accomplish this, we are working on infrastructure improvements at our manufacturing hubs from a global perspective.

In addition, to ensure customer satisfaction with our products, we are also deepening communication with the life sciences community through efforts such as improving our online catalog and holding events such as seminars and workshops.

We will continue implementing rigorous quality controls across all products and services, from reagents to CDMO services

Masanobu Kimura, Director & Head of Department of Drug Quality Assurance

Takara Bio supports the advancement of the global bioindustry by providing a wide range of products and services, from in vitro diagnostics and other reagents to CDMO services for regenerative medicine products. To maintain and improve the quality of these products and services, we work to acquire and maintain relevant certifications, such as ISO certification and GMP/GCTP compliance, and are building a quality assurance system across the entire company.

We are also working to build systems for collection, control, and management of safety data for ongoing clinical development projects in the gene therapy field to ensure the regulatory application process goes smoothly.

Established Takara Bio Group Basic Policy on Sustainability Management
Aims to Resolve Social Issues through Business Activities

Guided by our corporate philosophy of “contributing to the health of humankind through the development of revolutionary biotechnologies such as gene therapy,” and from the perspective of increasing our medium- to long-term corporate value, Takara Bio Group is working to solve various social challenges concerning sustainability, in the area of wellness as well as other areas, through our business activities. We aim to strike a balance between becoming a sustainable company and achieving sustained growth of Takara Bio Group. As part of this effort, we identified materialities (important issues) and are collaborating with stakeholders and partnering with Takara Holdings Group to carry out sustainability management to help solve social issues.

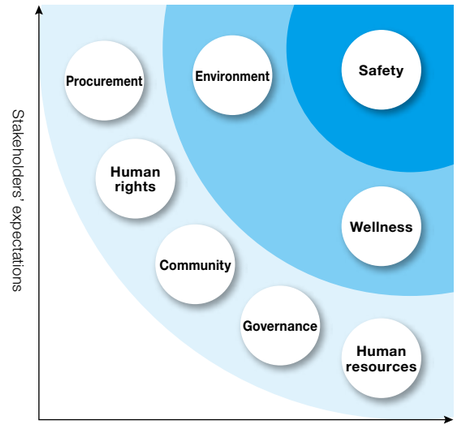
Identification of materialities (important issues)

We identified eight materialities that are most relevant to the Group’s business, with additional consideration to stakeholder expectations, that we will look to as we carry out our sustainability activities. As we tackle social issues with our central focus on these eight materialities, we aim to strike a balance between becoming a sustainable company and achieving sustained growth of Takara Bio Group.

Initiative areas for each materiality

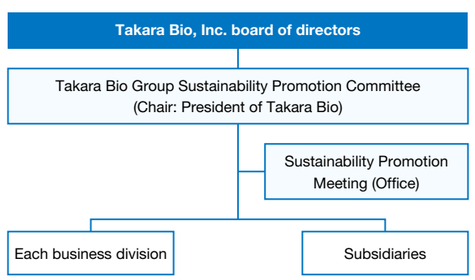
Safety	• Ensuring reliable quality
Wellness	• Support for the development of global life science research • Application of genetic analysis technology to testing and diagnostics • Initiatives for achieving gene therapies
Environment	• Response to climate change • Response to environmentally conscious product packages and packaging
Human resources	• Fostering human resources • Promoting the active involvement of diverse human resources • Achieving a comfortable workplace environment and a work-life balance
Governance	• Promotion of corporate governance • Promotion of compliance • Reinforcement of the risk management structure
Community	• Education for children • Contribution to the promotion of local communities and culture • Disaster assistance for large-scale disasters
Human rights	• Respect for human rights • Initiatives to identify risks to human rights
Procurement	• Collaboration with suppliers

Materiality matrix



System for implementation

The Group established a Takara Bio Group Sustainability Promotion Committee chaired by the President of Takara Bio to implement sustainability activities, and is carrying out initiatives related to each materiality.



Information about sustainability activities can also be found on the Takara Bio website.
https://www.takara-bio.co.jp

Safety

To ensure that our customers can use our products and services safely, we have established a basic policy on quality assurance and work to ensure safety in compliance with that policy.

Takara Bio Group Quality Assurance Policy (excerpt)

Basic Policy on Quality Assurance

- The Takara Bio Group provides high quality products and services that fulfill the trust and expectations of customers.
- The Takara Bio Group delivers products and services that are safe and that customers feel sure of.
- The Takara Bio Group complies with laws and regulations.
- The Takara Bio Group ensures the dissemination of this basic policy to each and every officer and employee in the Group and makes its execution certain.

Quality control efforts

Takara Bio and all its major global subsidiaries have acquired ISO certification, and are striving to improve the quality of products and services. We built a GMP/GCTP* compliant quality control system at our Center for Gene and Cell Processing, which provides CDMO services, and have become licensed as a manufacturer/distributor of specific processed cells/regenerative medicine products, pharmaceutical products (drugs, etc.), and in vitro diagnostics. Our lab for gene analysis services and genetic testing is also CAP-LAP certified and licensed as a clinical laboratory.

We will strive to maintain these certifications and licenses, as well as expand the scope of certification as needed.

*GMP: Standard for manufacturing control and quality control for pharmaceutical products
GCTP: Standard for manufacturing control and quality control for regenerative medicine products

ISO Certification status

Certified organization	Applicable standard
Takara Bio, Inc.	JIS Q 9001:2015 (ISO9001:2015)
	JIS Q13485:2018 (ISO13485:2016)
Takara Bio USA, Inc.	ISO13485:2016
Takara Bio Europe S.A.S	ISO9001:2015
Takara Biotechnology (Dalian) Co., Ltd.	ISO9001:2015
	ISO13485:2016
DSS Takara Bio India Private Ltd.	ISO9001:2015

Appropriate publication of product information

We actively work to publish documents related to product safety. We publish and provide information as appropriate in multiple languages in accordance with laws and regulations, including user manuals, CoA (Certificate of Analysis), SDS (chemical Safety Data Sheet), poisonous and deleterious substance labeling in accordance with the Poisonous and Deleterious Substances Control Law, and LMO (living modified organism) product labeling in accordance with the Cartagena Protocol.

Wellness

Through our efforts aimed at social implementation of advanced medicine, such as support of life science research and development of gene therapy, we are working to create a society in which people can stay well and enjoy life.

Support for the development of global life science research

Takara Bio Group offers a wide variety of products and services in the life sciences field, ranging from those for basic research to those with industrial applications. We are supporting the growth of research in the life sciences by providing universities and businesses around the world with a stable supply of these products.

Application of genetic analysis technology to testing and diagnostics

As demand for PCR testing grows amidst the pandemic, we are working to build up the testing system by strengthening our production system and providing a stable supply of PCR-related products both in Japan and internationally.

We have also actively expanded our genetic analysis technology to testing and diagnostics, and are helping people be well by expanding the scope of this technology.

Initiatives for achieving gene therapies

We have also been working to improve access to medical care for rare diseases by leveraging the biotechnology we have cultivated over many years in clinical development of gene therapy for rare cancers and other rare diseases. We are aiming to bring socially impactful regenerative medicine products such as gene therapies to market through our CDMO business to address unmet medical needs.

Environment

We consider the preservation of the global environment and the harmonious conduct of our business activities to be an important topic in the way we manage the company, and to that end we strive to observe the applicable environmental laws, ordinances, and regulations as we proactively take part in natural conservation activities and work to conserve resources and energy. We are working to reduce the environmental burden generated by all of our processes, ranging from R&D and the procurement of raw materials to production, distribution, sales, and consumption.

Environmental preservation strategies

The main facilities at Takara Bio headquarters account for a large percentage of Takara Bio Group's CO_2 emissions and water usage. At these buildings, we are implementing environmental preservation strategies such as use of construction design that incorporates new building techniques with high environmental performance.

Examples of environmental preservation strategies for Takara Bio headquarters

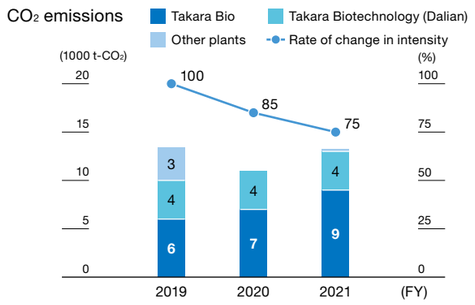
- Installed cogeneration systems
- Increased heat insulation in exterior walls and windows
- Used high-efficiency transformers
- Enabled visualization of the building's management system to optimize energy performance through the Building Energy Management System
- Designed buildings to prevent biohazard risk

Current CO_2 emissions and reduction targets (scope 1, 2*)

Takara Bio Group generated 13,000 t of CO_2 in fiscal 2021, which was a 2,000-t increase from the previous year. The main reason is that we began operations at a new plant at Takara Bio headquarters in January 2020. As Takara Bio Group expands its business, our CO_2 emissions are continuing to increase. However, we aim to consider environmental impact in our business activities, and have set targets for reducing emissions. Our target for fiscal 2031 is to reduce emissions per unit of revenue (emissions intensity) to 50% of that of fiscal 2019. Takara Holdings Group is also tackling environmental issues by aiming to reduce emissions to virtually zero by fiscal 2051.

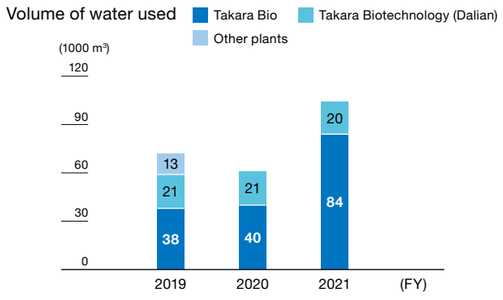
CO_2 emission reduction targets

- Reduce emissions per unit of revenue (emissions intensity) to 50% of that of fiscal 2019 by fiscal 2031
- Aim to reduce Takara Holdings Group emissions to virtually zero by fiscal 2051



Volume of water used

Takara Bio Group used 104,000 m^3 of water in fiscal 2021, which was a 43,000-m^3 increase from the previous year. The main reason is that we began operations at a new plant near Takara Bio headquarters in Japan.



Prevention of water pollution

Takara Bio Group is taking measures to ensure safety and environmental cleanliness by installing kill tank systems for wastewater treatment at facilities that handle biohazardous materials such as microorganisms, viruses, and genetically modified organisms and using these systems to treat contaminated wastewater under high heat and high pressure.

We are also preventing contamination of wastewater with harmful or biologically active substances by treating these substances as industrial waste.

Kill tank system for wastewater treatment at Takara Bio headquarters

*Scope 1: Greenhouse gases directly emitted from our facilities
Scope 2: Indirect emissions from electricity, heat, and steam supplied by other companies

Human resources

We respect our employees and aim to create a work environment where employees can work cheerfully and enthusiastically, create a nurturing work culture, and promote a balance between corporate, social, and private life within that environment and culture.

Fostering human resources

We have put in place systems and training programs for our personnel as we strive to achieve a corporate climate that can best reflect the skills possessed by and challenges faced by our employees in our management and business practices.

Our training program includes stratified training by job level and years of service, as well as objective-based training.

Examples of stratified training programs

Training	Objectives and details
Training for new hires, 3rd-year employees, 6th-year employees, and newly appointed managers	Training on knowledge and skills required for each job level
OJT leader training	Training on the role of OJT leaders (veteran employees assigned to individual new hires) and guidance methods
Compliance leader training	Group training on compliance for employee representatives selected at each workplace

Examples of objective-based training programs

Intended participants	Objectives and details
All employees	Fire prevention training, AED education and training, safety confirmation
	Compliance education
	Study seminar to improve IT skills
	Information security education
Young tech-oriented employees	Intellectual property training
Marketing Division employees	Sales training
Employees who perform manufacturing and quality control tasks	GMP education and training, ISO education and training

Promoting the active involvement of diverse human resources

The existence of diverse viewpoints and senses of values that reflect different experiences, technical skills, and attributes regardless of gender, nationality or other traits among employees is the strength that allows a company to continuously grow.

We believe that active involvement of diverse human resources at Takara Bio is essential to achieving continued growth going forward.

Employee composition at Takara Bio (not the Group)

		FY2019	FY2020	FY2021
Employees with disabilities (%)		2.2%	2.2%	2.9%
Women (%)	All employees	40.2%	42.0%	42.6%
	New graduates	52.0%	63.2%	60.0%
	Managerial positions	19.5%	19.5%	19.7%

Achieving a comfortable workplace environment and a work-life balance

We are working hard to put workplace and labor environments in place that will allow our employees to work comfortably, and are crafting systems to ensure that all our employees can work enthusiastically while maintaining a balance between their work and their personal lives in keeping with their individual lifestyles.

Crafting workplace and labor environments	Regular health checkups, mental health care, health consultations by occupational physicians, help lines and internal reporting systems (in Japan and at international subsidiaries)
Work-life balance	Flex time, temporary part-time work for parents, parental and caregiving leave, consultations for employees taking parental leave, reformation of long working hours, "no overtime day," work-from-home

Community

We aim to contribute to local development and revitalization through our interactions with the local community. We are also engaged in activities aimed at advancing the life sciences industry through education and academic support.

Education of the next generation

Every year, Takara Bio executives and employees guest lecture at local universities about the latest trends and future outlook in topics such as gene therapy and regenerative medicine from a corporate and business perspective. We also support students in career planning by dispatching new hires who volunteered to visit their alma maters to participate in opportunities to discuss topics such as their current job duties, why they joined Takara Bio, and how they feel about their work.

We even visit local elementary schools and give presentations that explain our business to students in an easy-to-understand way. These efforts are popular among community members and they have expressed their hope that we continue them.

Contribution to the promotion of local communities and culture

We support local communities through activities such as local cleanup events, and also contribute relief funds and hold volunteer activities to support those affected by major disasters.

Human rights

We respect the human rights of all stakeholders and are engaged in various human rights-related initiatives including education and training.

Takara Group Human Rights Policy (excerpt)

Recognizing that the Takara Group may potentially affect the human rights of various stakeholders, including business partners, customers, and local communities, in addition to our employees, through our business activities, we respect human rights as set out in the United Nations' International Bill of Human Rights and the International Labour Organization (ILO) Declaration on Fundamental Principles and Rights at Work.

This Policy applies to all officers and employees of the Takara Group. We also request business partners to support and comply with this Policy.

Respect for human rights

Education on understanding and respect of human rights and cultural diversity

We carry out programs to deepen understanding and respect of human rights and cultural diversity (multiculturality) and conduct awareness-raising activities as part of stratified training and compliance training.

Recruitment activities without discrimination

We adhere to the Act on Securing, Etc. of Equal Opportunity and Treatment between Men and Women in Employment. To ensure thorough consideration for human rights, we provide our employees involved in hiring with education on human rights using manuals and other materials.

Initiatives to prevent harassment

To prevent sexual harassment, power harassment, and other forms of harassment concerning pregnancy, childbirth, child rearing, and care giving, we have established a consultation and complaint office at each workplace, in addition to a Mediation Committee.

Protect personal information and privacy

We comply with laws concerning personal information and other relevant laws and ordinances, clarify our Basic Policy on the Protection of Personal Information, and strive to continue enhancing our structure for the protection of personal information.

Initiatives to identify risks to human rights

Establish a structure to identify and evaluate risks to human rights

We will collect information to identify human rights risks of the Group (human rights due diligence) and investigate human rights risks of the entire value chain in which we are involved. We will then create a structure to identify and evaluate human rights risks of the entire Group.

Procure-ment

We aim to realize sustainable procurement by ensuring the safety and quality of raw materials and more, and by also considering the social responsibility of the entire supply chain, including consideration for the environment and human rights as well as compliance with laws and social ethics.

Takara Group Procurement Policy

1. **Ensuring safety and quality**
   In accordance with the Takara Group Quality Policy, we will promote activities aimed at ensuring a high level of safety and quality.
2. **Consideration for the environment**
   Based on the Takara Group Environmental Policy, we will engage in activities with consideration for the global environment.
3. **Consideration for human rights**
   In accordance with the Takara Group Human Rights Policy, we will engage in activities with consideration for human rights.
4. **Compliance with laws and social ethics**
   In accordance with the Takara Group Compliance Action Guidelines, we will comply with laws and social ethics. We will not request entertainment or gifts from suppliers, nor will we be the recipient of entertainment that exceeds the boundaries of common sense.
5. **Equitable and fair transactions**
   We will treat all suppliers with common sense and honesty and conduct equitable and fair transactions. When selecting suppliers, we will make our decisions after equitable and fair comparisons and evaluations, based on quality, price, delivery date, technical capabilities, supply capacity and other conditions.
6. **Maintaining information security**
   We will appropriately manage confidential information and personal information obtained during procurement activities.
7. **Expectations of suppliers**
   With regard to the above, we expect the same considerations from our suppliers, and will endeavor to promote initiatives throughout the entire supply chain.

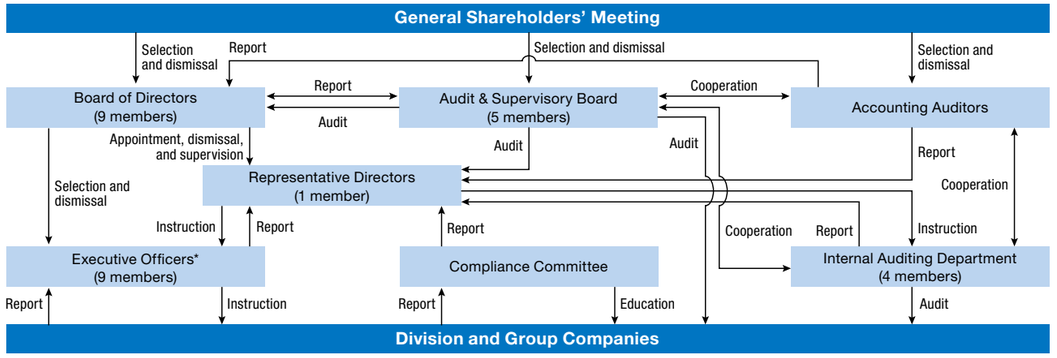
Collaboration with suppliers

We are currently drafting guidelines for sustainable procurement in each procurement area. We will make our business partners aware of these guidelines and request their compliance with the guidelines, and collaborate with suppliers to resolve issues.

Gover-nance

We will pursue sustainable growth and enhancement of our corporate value in the medium- to long-term by fulfilling our social responsibility as a corporation, and by meeting the expectations of our various stakeholders, including our shareholders.

Diagram of Corporate Governance Structure As of June 2021



*Excludes those who are also directors

About Our Parent Company (Takara Holdings)

As of March 31, 2021, Takara Holdings Inc. is the parent company of Takara Bio, possessing 60.93% of the voting rights. The following section describes the relationship between the two companies.

(1) The position of Takara Bio in Takara Holdings Inc.

Takara Bio was established as a 100% subsidiary of Takara Holdings Inc. spun off during the extraordinary general meeting of stockholders of Takara Shuzo Co., Ltd (the current Takara Holdings Inc.) on February 15, 2002, in order to maximize the value of the businesses it was engaged in: the alcoholic beverages and foods business and the bio business. Since then, via allocation of new stocks to a third party and public stock offering, Takara Holdings now owns 60.93% of Takara Bio's voting shares. The Takara Holdings Group is made up of the holding company Takara Holdings, 60 subsidiaries, and two affiliated companies. Among those, Takara Bio is positioned as a subsidiary specializing in biotechnology, and promotes its bio business along with eight other subsidiaries.

(2) About corporate management of the Takara Holdings Inc.

Takara Holdings Group has established and put into operation Group Company Management Rules from the perspective of consolidated business management. These are intended to maintain the individuality and autonomy of each of the Group companies, while maximizing corporate value for the Group as a whole. Takara Bio has also applied the same rules and is reporting the matters resolved at meetings of the Board of Directors, but these resolutions do not need prior approval, and we are operating our business independently. While there are other meeting structures in place in addition to this one, all are intended for business reporting, and none have infringed on Takara Bio's autonomy or independence.

Our Corporate Governance

In order to achieve sustainable growth and enhance corporate value over the medium- to long-term, the Takara Bio Group recognizes that it should endeavor to cooperate with various stakeholders, including shareholders, employees, customers, creditors, and local communities in an appropriate manner. To achieve this, our corporate governance structure must promote honesty and fairness throughout all our corporate activities at all times, which is why Takara Bio is working toward establishing the specific policies.

Corporate Governance Structure

Our system is set up so that directors make decisions in an agile manner with a clear sense of ownership and speed and supervise execution of business, while our external directors, who are highly independent experts experienced in and knowledgeable about the company's business, partner with the Audit & Supervisory Board to audit and supervise execution of business.

Director and Board of Directors

The Board of Directors of Takara Bio is composed of nine individuals, of whom three are external directors. In addition, in order to rapidly respond to the management environment and to clarify the management responsibilities of a director, the term of office of a director has been set to one year.

Audit & Supervisory Board

The Audit & Supervisory Board of Takara Bio is composed of five individuals, of whom three are external auditors. The auditors and Audit & Supervisory Board of Takara Bio are to make appropriate decisions from an independent and objective standpoint regarding their role and the performance of their duties. In addition, the auditors must attend meetings of the Board of Directors and various important management meetings as well as conduct appropriate financial and operational audits via an exchange of opinions, etc., between management and the internal auditing department, etc., and they must also make a variety of proposals to management when they are determined to be needed.

Messages from External Directors

Meeting social demands with our drug discovery business as our driving force

Nobuko Kawashima

Appointed June 2016/Board of Directors meeting attendance in FY2021: 12 of 12 (100%)

Over this past year, the global community has faced an unprecedented crisis, and now it seems like nothing can surprise us anymore. Throughout this time of crisis, Takara Bio has made major contributions to COVID-19 measures by providing its superior PCR technology, which is the company's particular strength, to meet Japan's needs. Due in part to this series of actions, we have seen the company name in newspapers and other media considerably more than before, and it seems that general awareness of Takara Bio is increasing. Of course, we do not intend to be swayed too much by this newfound fame. We must continue to focus our efforts on our existing drug discovery business using biotechnology to develop treatments for cancer and other diseases, and our determination to do so can be clearly observed in our board of directors and others. I believe that the clearer that driving force and our key challenges are, the better we can make strategic moves if we are forced to change course slightly.

Our responsibility as a bearer of biotechnology

Kazuko Kimura

Appointed June 2019/Board of Directors meeting attendance in FY2021: 12 of 12 (100%)

This age of COVID-19 has brought with it greatly increased responsibility for companies that have biotechnology.

We are currently faced with a seemingly endless pandemic, and in the future humanity will continue to be threatened by yet-unknown infectious diseases. Biotechnology, which provides tests, treatments, and prevention methods, is the weapon we use to fight these diseases. Takara Bio has used its knowledge, technology, and talent cultivated over many years to meet the demands of the age, and has not only broken new ground but also pushed forward with an eye to future developments. The success of Takara Bio in the biotechnology business is in line with the UN SDGs, particularly Goal #3, "to ensure healthy lives and promote well-being for all at all ages." I hope that we will continue to wholeheartedly anticipate future biotechnology needs and deepen the field. Once we have reliably done so, we could broaden our scope of CSR activities, for example, to use our products to provide opportunities for disadvantaged people in Japan and abroad who have not been able to reap the benefits of cutting-edge technology. I think that this would further highlight our initiatives related to the SDGs, and could further improve understanding of our company.

The importance of biotechnology to humankind

Noriomi Matsumura

Appointed June 2020/Board of Directors meeting attendance in FY2021: 10 of 10 (100%)

Talking and interacting with others is a fundamental act and a source of happiness for human beings, but the pandemic turned that upside down. I work at a university hospital that treats critically ill COVID-19 patients, and am acutely aware of the importance of Takara Bio's biotechnology in getting through the pandemic. I am also incredibly honored to assist with the management of Takara Bio as an external director during this critical time. During the pandemic, Takara Bio has been involved in developing and producing PCR reagents and developing vaccines, and has truly projected a strong presence as a company that can respond to social needs. Biotechnology is making rapid progress, and is becoming increasingly important to humankind. I would like to contribute from the perspective of a physician and medical researcher to help Takara Bio keep pace with those advances.

Officer compensation

Officer compensation is determined by the President with authorization of the Board of Directors based on performance evaluation methods approved by the Board of Directors, within the range of the amount for each approved by the general shareholders' meeting, and with consideration to a comprehensive array of factors such as job title and contribution to company performance. Compensation for officers consists of a fixed amount of compensation plus performance-linked compensation, while compensation for external directors and external auditors consists solely of a fixed amount of compensation within the range approved by the general shareholders' meeting.

Compensation of directors and auditors (FY2021)

Officer category	Total compensation by type (millions of yen)		Total compensation (millions of yen)	Number of officers receiving this compensation
	Fixed compensation	Performance-linked compensation		
Directors (excluding external directors)	161	117	278	6
Auditors (excluding external auditors)	30	–	30	2
External Directors	19	–	19	4*
External Auditors	20	–	20	3

*Includes one external director who resigned at the time of the 18th general shareholders' meeting held June 23, 2020

Promotion of compliance

Takara Bio has established its own Compliance Committee, with the President as the Chairperson in order to enhance the system for promoting compliance for the Group as a whole.

In addition, Takara Holdings Group has established its own Guiding Principles for Compliance Conduct. Each of the Group companies suitably abides by the law and social ethics and undertakes risk management, enabling the Takara Group as a whole to fulfill its corporate social responsibility and to improve its corporate value.

Takara Group Guiding Principles for Compliance Conduct

Basic Policy

With the aim of realizing our corporate philosophy, which is "Contributing to the creation of a vital society and a healthy lifestyle through our fermentation technology and biotechnology in a way that achieves harmony with nature," the Takara Group will always conduct trustworthy and fair corporate activities in accordance with our code of conduct, "what makes consumers full of life makes me full of life."

(1) We will comply with laws and regulations in Japan and overseas, fully recognize social ethics, and act with common sense and responsibility as a member of society.

(2) We will work to lower environmental burdens, and contribute to the development of life science that values the dignity of life.

(3) We will conduct sustainable business activities that are widely useful to society by pursuing profit through fair competition rather than pursuing profit in a manner contrary to these Action Guidelines.

(4) We will comply with employment regulations, and will not engage in any unfair or dishonest practices in violation of employment regulations.

(5) We will always draw a line between public and private matters, and will not pursue personal gain by using corporate assets, information, business authority, or position.

Compliance education

In order to enhance employees' compliance awareness, the Takara Group issues compliance newsletters that deal with compliance-related subjects familiar to its employees and offers an e-learning course every month. As stratified training, we also provide risk compliance seminars for top management led by guest specialists, annual group training for risk compliance seminars for top management led by guest specialists, annual group training for risk compliance leaders who promote workplace compliance education for each job level, and well as training sessions for new managers, and new hire training.

Appropriate operation of the whistleblowing system

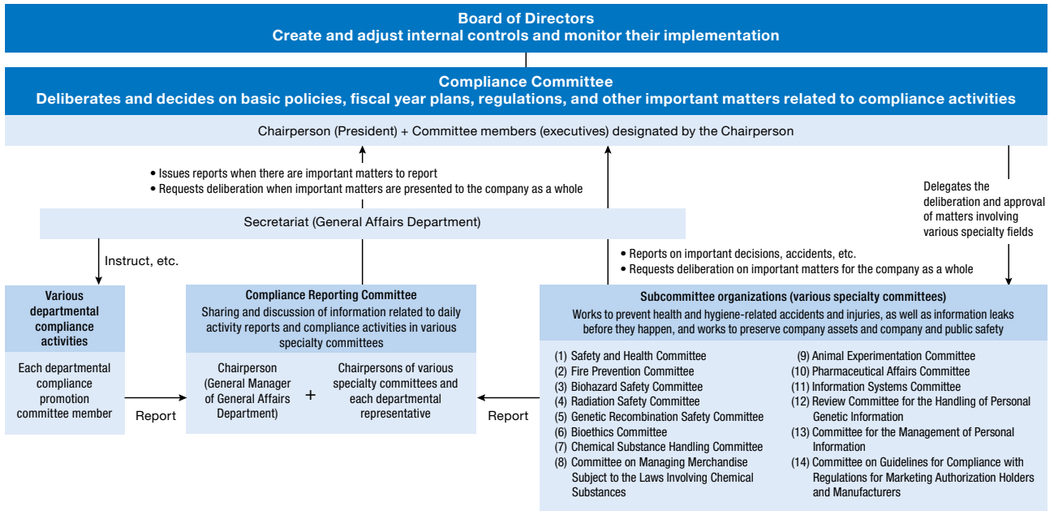
We have two Takara Group helplines in place inside and outside the Company (i.e., third-party organizations), as contacts for whistleblowers in the event that they have noticed any legal infringements or unfair practices. We operate these helplines in accordance with Japan's Whistleblower Protection Act and the Helpline Rules in order to ensure that whistleblowers do not receive disadvantageous treatment due to the reports they have made. The Company gives full consideration to maintaining confidentiality when investigating reports and takes appropriate action based on confirmed facts.

Our Group companies in overseas locations also have their local whistleblowing hotlines and have established and operate processes that allow their local employees to directly contact the helpline in Japan for reporting and consultation through a third-party organization.

Risk Management

The Group carries out regular workplace inspections in normal times in order to understand and strategize for risks, and the results of those inspections are discussed at the Compliance Committee. We are also proactive in risk management, such as our revision of strategies for business continuity planning (BCP) that takes into account events such as large-scale disasters and systems that allow for executive and employee safety confirmation.

Organizational Setup for Compliance-related Activities



List of Themes, Measures, and Targets for Each Materiality

Materiality	Theme	Measure	Targets
Safety	Ensure product safety	Maintain quality management system certifications (ISO9001, etc.)	• Maintain current ISO certifications at plants and work to improve quality and customer satisfaction. Expand scope of ISO certification as necessary. • Maintain business licenses and registrations.
		Achieve and maintain compliance with relevant quality, manufacturing, and safety standards such as GMP/GCTP, and third-party certification	
		Appropriately disclose product information	Provide information about our products in multiple languages (Japanese, English, and Chinese) through Safety Data Sheets (SDS) by 2025.
Wellness	Support for the development of global life science research	Provide extensive support for the development of life science research and industry	Continue making improvements to core manufacturing facilities in Japan, China, the U.S., and Europe and other regions with the aim of ensuring a stable product supply, and work toward optimization, to support advancement of the life sciences on a global scale.
		Contribute to the life science community	• Disseminate information about biotechnology fundamentals and the latest technology by holding seminars and workshops. • Commercialize promising academic discoveries through open innovation. • Promote social understanding of biotechnology.
	Application of genetic analysis technology to testing and diagnostics	Supply testing and diagnostic kits for viruses, etc.	"Glocalize" our product development scope to go beyond virus testing kits for infectious diseases with broad worldwide impact and add products tailored to region-specific characteristics and needs.
	Initiatives for achieving gene therapies	Gene therapy technology development and social implementation for cancer and other targets	• Carry out gene therapy development projects ourselves and through partnerships. • Support development and manufacturing of regenerative medicine products (CDMO business).
Environment	Response to climate change	Reduce CO_2 emissions from production process	Reduce Takara Bio Group's CO_2 emissions intensity (emissions per unit of revenue) to 50% of that of fiscal 2019 in fiscal 2031.
	Response to environmentally conscious product packages and packaging	Develop environmentally conscious products	• Start switching paper packaging to FSC-certified paper, with the aim of 100% usage by fiscal 2026. • Switch 100% of aluminum packaging to single-sided aluminum pouches by fiscal 2026. • Switch 100% of ink used for paper packaging to vegetable oil-based ink by fiscal 2026.
Human resources	Fostering human resources	Implement measures to foster human resources who will be responsible for the next generation	• Foster human resources who can achieve global business growth and bring the Group into the next generation by continually holding stratified trainings for new hires and managers as well as educational sessions to train the next generation of leaders.
		Foster human resources who will achieve global business growth (global human resources)	
		Foster human resources using Takara Holdings Corporate History Museum, our training facility	
	Promoting the active involvement of diverse human resources	Promoting the active involvement of female employees	• Increase the percentage of women in managerial positions. • Create opportunities to continue working until age 70. Start an initiative to create opportunities to work from age 65 to 70 in fiscal 2022. • Maintain the percentage of employees with disabilities at 2.3% or higher (percentage mandated by law as of April 2021). • Further pursue mid-career hiring to acquire a diverse range of human resources. • Realize a fair hiring system that does not discriminate by nationality, race, gender, or disability, and build a working environment where all these groups respect one another.
		Promote the active involvement of senior human resources	
		Promote the hiring of people with disabilities	
	Achieving a comfortable workplace environment and a work-life balance	Ensure workplace safety and sanitation	• Reduce total working hours compared with fiscal 2021 figures. • Increase percentage (and days) of paid holidays taken compared with fiscal 2021 figures. • Maintain percentage of employees returning to work after childcare leave at 100%. • Effectively utilize work-from-home systems. • Raise awareness and provide information about parental and childcare leave systems by the end of March 2025. • Establish a consultation service for employees who are pregnant or are returning to work after parental or childcare leave before the end of March 2025.
		Comply with labor-related laws and regulations	
		Prevent long working hours	
		Promote diverse working styles	
Governance	Promotion of corporate governance	Establish an optimum corporate governance structure	Maintain appropriate corporate governance with the aim of achieving sustained growth and medium-term growth in corporate value.
	Promotion of compliance	Reinforce the compliance promotion structure	Ensure that each officer and employee acts fully in accordance with the company's Compliance Action Guidelines and promote compliance across the entire Group, including international subsidiaries, to realize our corporate philosophy. • Distribute the Takara Group Compliance Action Guidelines, which describe how to behave in accordance with laws and social ethics, and with which every individual employee of the Takara Group should comply, in order to achieve a high level of compliance. • Regularly hold Risk Compliance Committee meetings (generally twice a year). • Hold training sessions for each job level to increase officer and employee awareness of compliance (generally once a year). • Hold workplace compliance education sessions on key compliance-related topics (generally four times a year). • Prevent illegal and inappropriate behavior, as well as recurrence of such behavior, by properly employing the internal reporting system and responding quickly and appropriately to internal reports.
		Implement compliance education	
		Appropriately operate the whistleblowing system	
	Reinforcement of the risk management structure	Promote risk management (normal risk management)	Work to prevent risk manifestation and reduce corporate risks in Japan and abroad, and build a system for responding quickly and appropriately in times of disasters and other emergencies. • Monitor risk management status at each subsidiary and office through workplace inspection reports, risk compliance checklists, and employee hearings, and use findings to prevent risk manifestation and reduce risk (generally once a year). • Regularly hold emergency drills (safety confirmation training, fire prevention training, AED training, etc.) (generally once a year).
		Promote crisis management (emergency risk management)	
Community	Education for children	Make educational visits to local elementary schools	Hold lectures and classes at nearby educational institutions. (Continue to announce seminars on gene therapy and regenerative medicine, as well as hands-on career planning activities.)
	Contribution to the promotion of local communities and culture	Participate in local cleaning activities and support local communities	Continue to volunteer for local cleaning activities and participate or cooperate in the community by activities such as sponsoring community events.
	Disaster assistance for large-scale disasters	Provide donations, water supply, and volunteer activities to disaster-stricken areas	Provide assistance such as supplying water and dispatching volunteers to areas struck by major disasters as much as possible and as quickly as possible.
Human rights	Respect for human rights	Conduct human rights education at new hire training and stratified training sessions	Aim to maintain a workplace that respects diversity (gender, age, race, sexual orientation, gender identity, disability, etc.), personality, and individuality, without discrimination or harassment.
		Understanding and respect for multiple cultures (multinational cultures)	
		Recruitment activities without discrimination	
		Initiatives to prevent harassment	
		Protect personal information and privacy	
	Initiatives to identify risks to human rights	Establish a structure to identify and evaluate risks to human rights	Create a process to identify and evaluate risks to human rights across the entire Takara Group value chain (human rights due diligence process) by fiscal 2023, and begin efforts to identify and evaluate human rights risks by fiscal 2024.
Procurement	Collaboration with suppliers	Discuss content of guidelines for sustainable procurement	Create procurement guidelines, spread awareness among business partners, and request compliance by 2025.

ESG Indices

Governance-related information—Number of external directors and external Audit & Supervisory Board members

		FY2019	FY2020	FY2021
Directors		8	9	9
	Internal directors	6	6	6
	External directors	2	3	3
	Ratio of external directors (%)	25	33	33
Audit & Supervisory Board members		5	5	5
	Internal Audit & Supervisory Board members	2	2	2
	External Audit & Supervisory Board members	3	3	3

Employee information (Takara Bio Group)

Item	Breakdown		FY2019	FY2020	FY2021
No. of employees by region	Japan		480	517	570
	Overseas	U.S.	207	206	202
		China	588	589	587
		Europe	71	81	88
		Other*	89	92	92

*Asia excluding Japan and China

Employee Information (Takara Bio)

Items	Breakdown	FY2019	FY2020	FY2021
No. of employees by region	Male	287	300	327
	Female	193	217	243
No. of new graduate hires	Male	12	14	6
	Female	13	24	9
Diversity	Employees with disabilities (%)	2.2	2.2	2.9
	Women in managerial positions (%)	19.5	19.5	19.7
Status of employees	Average years of service	13 years and one month	13 years and one month	12 years and eight months
	Average age	40 years and 11 months	40 years and 10 months	41 years and 0 months
	Average annual remuneration (Tens of thousands of yen)	694	694	695
	No. of women who have taken childcare leave	11	7	5
	No. of men who have taken childcare leave	1	0	6
	Women who returned to work after taking childcare leave (%)	100	100	100
	Monthly average of overtime hours	17.75	20.88	25.55
	Annual paid holidays taken (%)	10.6	10.8	9.8
	Turnover* (%)	6.7	1.2	1.8
	Average years of employment (male)	13.8	14.1	13.7
	Average years of employment (female)	12.1	11.8	11.4
Industrial safety and health	No. of work-related injuries (including minor injuries)	0	6	2
	Frequency	0	0	0
	Severity	0	0	0

*Turnover of newly-graduated employees who leave within three years of service

Environment-related Information

Items	Applicable companies	FY2019	FY2020	FY2021
CO_2 emissions (t-CO_2) (Scope 1,2)	Takara Bio	5,894	6,822	8,585
	Takara Biotechnology (Dalian)	3,869	4,039	4,058
	Other offices	3,425	0	187
Waste emissions (t)	Takara Bio	129	178	231
	Takara Biotechnology (Dalian)	74	74	88
Amount of chemical substances handled (under PRTR Law) (kg)	Takara Bio	76	34	97
Volume of water used (m^3)	Takara Bio	38,246	39,784	84,190
	Takara Biotechnology (Dalian)	21,062	21,428	19,963
	Other offices	12,993	0	75

Executives

As of June 30, 2021

Board of Directors

Hisashi Ohmiya
Chairman, Director

Apr. 1968 Joins Takara Shuzo Co., Ltd. (currently Takara Holdings Inc.)
May 1974 Director, Takara Shuzo Co., Ltd.
Jun. 1982 Managing Director, Takara Shuzo Co., Ltd.
Jun. 1988 Senior Managing Director, Takara Shuzo Co., Ltd.
Jun. 1991 Vice President, Takara Shuzo Co., Ltd.
Jun. 1993 President, Takara Shuzo Co., Ltd.
Apr. 2002 Chairman (incumbent)
Chairman, Takara Bio Inc.
President, Takara Shuzo Co., Ltd.
Jun. 2012 Chairman, Takara Holdings Inc. (incumbent)
Chairman, Takara Shuzo Co., Ltd. (incumbent)
Jul. 2017 Chairman, Takara Shuzo International Co., Ltd. (incumbent)

Koichi Nakao (CEO)
President & CEO

Apr. 1985 Joins Takara Shuzo Co., Ltd. (currently Takara Holdings Inc.)
Apr. 2002 Director
Jun. 2003 Managing Director & Executive Officer
Jun. 2004 Senior Managing Director & Executive Officer
Apr. 2006 Senior Managing Director & Executive Officer, COO
Jun. 2007 Vice President & Executive Officer, COO
Jun. 2008 Vice President, COO
May 2009 President (incumbent)
President, Takara Bio USA Holdings Inc. (incumbent)
Jun. Director, Takara Holdings Inc. (incumbent)
Jun. 2015 President & CEO

Junichi Mineno (COO)
Director & Senior Corporate Officer

Apr. 1984 Joins Takara Shuzo Co., Ltd. (currently Takara Holdings Inc.)
Apr. 2011 Executive Officer
Jun. 2012 Senior Executive Officer
Jun. 2014 Managing Director
Jun. 2015 Managing Director & Senior Executive Officer
Jun. 2019 Director (incumbent) & Senior Executive Officer (incumbent)

Yoh Hamaoka (CFO)
Director & Senior Corporate Officer

Feb. 2000 Joins Takara Shuzo Co., Ltd. (currently Takara Holdings Inc.)
Apr. 2004 Executive Officer
Jun. 2009 Senior Executive Officer
Jun. 2021 Director (incumbent) & Senior Executive Officer (incumbent)

Masanobu Kimura
Director & Senior Executive Officer

May 2013 Joins Takara Bio Inc.
Jun. 2016 Executive Officer
Jun. 2017 Director (incumbent) & Senior Executive Officer (incumbent)

Tsuyoshi Miyamura
Director & Senior Executive Officer

Apr. 1988 Joins Takara Shuzo Co., Ltd. (currently Takara Holdings Inc.)
Jun. 2009 Executive Officer
Jun. 2014 Senior Executive Officer (incumbent)
Jun. 2018 Director (incumbent)

Nobuko Kawashima
Director (External Director)

Apr. 1986 Joins The Long-Term Credit Bank of Japan (currently Shinsei Bank, Limited)
Sep. 1987 Joins Dentsu Communication Institute Inc.
Sep. 1995 Research fellow at the Centre for Cultural Policy Studies of the University of Warwick
Apr. 1999 Full-time lecturer with the Faculty of Economics at Doshisha University
Apr. 2004 Professor with the Faculty of Economics at Doshisha University (incumbent)
Jun. 2016 Director (incumbent)
Jun. 2021 External director, TOKAI Holdings Corporation (incumbent)

Kazuko Kimura
Director (External Director)

Apr. 1976 Joins the Ministry of Health and Welfare (currently Ministry of Health, Labour and Welfare)
Jul. 1996 Seconded to the pharmaceutical department of the World Health Organization
Jul. 1999 Seconded to the Organization for Pharmaceutical Safety and Research
Apr. 2000 Professor of International Medical Research Laboratory, Institute of Medical, Pharmaceutical and Health sciences, Kanazawa University
Jun. 2013 Director (External Director), Alfresa Holdings Corporation
Sep. Representative Director, Medicines Security Workshop
Apr. 2017 Professor Emeritus at Kanazawa University (incumbent)
Oct. Specially Appointed Professor with the Graduate School of Medical Sciences at Kanazawa University (incumbent)
Jun. 2019 Director (incumbent)
Jun. 2021 External director, Mitsubishi Logistics Corporation (incumbent)

Noriomi Matsumura
Director (External Director)

Apr. 2017 Professor with the Department of Obstetrics & Gynecology, Faculty of Medicine, at Kindai University (incumbent)
Jun. 2017 Vice chairperson of Board Certification Committee at Japan Society of Obstetrics and Gynecology (incumbent)
Dec. 2018 Director and TR Committee member of Japanese Gynecologic Oncology Group
Jun. 2020 Director (incumbent)
Jul. 2020 Board Member, Japan Society of Gynecologic Oncology (incumbent)

Audit & Supervisory Board Members

Akihiko Kita
Standing Audit & Supervisory Board Member

Apr. 1984 Joins Takara Shuzo Co., Ltd.
Apr. 2014 Executive Officer
Jun. 2016 Standing Audit & Supervisory Board Member (incumbent)

Masahide Tamaki
Standing Audit & Supervisory Board Member

Apr. 1983 Joins Takara Shuzo Co., Ltd.
Apr. 2007 Executive Officer
Jun. 2016 Senior Executive Officer
Jun. 2019 Standing Audit & Supervisory Board Member (incumbent)

Kunihiko Kamada
External Audit & Supervisory Board Member

Apr. 1992 Registered as an attorney at law (Osaka Bar Association)
Mar. 1993 Registered as a patent attorney
Apr. 2007 Part-time lecturer at Meijo University
Jan. 2011 Daiichi Law Office, P.C. (incumbent)
Jun. 2016 Audit & Supervisory Board Member (incumbent)

Yasuo Himeiwa
External Audit & Supervisory Board Member

Aug. 1983 Joins the accounting firm of Peat Marwick Mitchell & Co. (currently KPMG)
Aug. 1990 Registered as a Certified Public Accountant of Japan
Aug. 1994 European Director at KPMG Project Japan
Jan. 1996 Century Audit Corporation (currently Ernst & Young ShinNihon LLC)
Feb. 2001 Senior partner at Ernst & Young ShinNihon LLC
Sep. 2003 Partner at KPMG AZSA LLC
Jul. 2009 Director, AZSA LLC Osaka GJP (Global Japanese Practice)
May 2015 National Employee Association Chairman, KPMG AZSA LLC
Jun. 2016 Director, Himeiwa Accounting Office (incumbent)
Audit & Supervisory Board Member (incumbent)
Jun. 2017 Outside Director (Member of Audit & Supervisory Committee), Sharp Corporation (incumbent)
Jun. 2020 Outside Director (Member of Audit & Supervisory Committee), IDEC Corporation (incumbent)

Masaaki Makikawa
External Audit & Supervisory Board Member

Apr. 1996 Professor with the Faculty of Science and Engineering, Ritsumeikan University
Apr. 2003 Head of the Liaison Office, Biwako-Kusatsu Campus, Ritsumeikan University
Apr. 2011 Visiting Professor with the Graduate School of Medicine, Osaka University (incumbent)
Apr. 2012 Dean of the Research Division, Ritsumeikan University
Apr. 2017 Specially Appointed Professor with the Faculty of Science and Engineering, Ritsumeikan University (incumbent)
Jun. 2017 Audit & Supervisory Board Member (incumbent)
Jul. 2017 Special Professor with the Faculty of Science and Engineering (Assistant Director), Ritsumeikan University (incumbent)
Apr. 2021 President, Hatsushiba Gakuen (incumbent)

Executive Officers

Mutsumi Sano
Senior Executive Officer

Kazuki Yamamoto
Senior Executive Officer

Katsuhiko Kusakabe
Senior Executive Officer

Akira Kodera
Executive Officer

Noritaka Nishiwaki
Executive Officer

Masanari Kitagawa
Executive Officer

Nobuto Koyama
Executive Officer

Takuya Kakemi
Executive Officer

Kyoko Nakajima
Executive officer

Contents of the attached document

Net sales

Based on the six-year "Long-Term Management Plan 2026" ending in FY2026 and the three-year "Medium-Term Management Plan 2023" ending in March 2023, our Group has been promoting initiatives aimed at making us a drug development company that forges ahead with creative drug technology development and the continuous creation of new modalities via our research reagent, scientific instrument, and CDMO businesses. In addition, we have proactively engaged in actions such as the stable supply of products related to PCR testing for COVID-19 and the development of manufacturing systems for regenerative medicine products, including vaccines.

Though sales of genetic therapy decreased relative to the previous fiscal year, in the consolidated fiscal year under review sales of research reagents, scientific instruments, and contract services increased. In the area of research reagents and scientific instruments, PCR test-related products for COVID-19 contributed in part to the increase. As a result, net sales increased 33.3%, year-over-year, to ¥46,086 million.

Income

Cost of sales increased 5.6%, year-over-year, to ¥14,214 million due to a decrease in the cost of sales ratio as a result of changes in the sales composition and an increase in the production capacity utilization ratio among other factors, while gross profit increased 51.0%, year-over-year, to ¥31,872 million. Selling, general and administrative (SG&A) expenses increased 20.8% year-over-year to ¥17,919 million due to an increase in expenses such as research and development costs, and operating income increased 22.4% year-over-year to ¥13,952 million.

Other income (expenses) increased by ¥441 million year-over-year due to factors such as a decrease in impairment losses on fixed assets and an increase in loss on liquidation of business.

This resulted in income before income taxes increasing by 49.4% year-over-year to ¥13,552 million. Also, net income attributable to owners of the parent increased 49.9% year-over-year to ¥9,547 million.

Financial Condition

Total assets as of the end of the fiscal year ended March 31, 2021 on a consolidated basis were ¥89,750 million, a year-over-year increase of ¥14,740 million. This owed mainly to an increase of ¥8,845 million in cash and cash equivalents, and an increase of ¥5,552 million in property, plant and equipment resulting from the acquisition of assets such as land and buildings for the new worksites of Takara Bio USA, Inc., and manufacturing facilities for Takara Bio in Japan.

Total liabilities as of the fiscal year-end were ¥15,448 million, a year-over-year increase of ¥7,030 million. This was primarily due to increases of ¥2,396 million in other current liabilities, ¥2,462 million in unpaid corporate taxes, and ¥1,050 million in notes and accounts payable-trade.

Total net assets as of the fiscal year-end were ¥74,302 million, a year-over-year increase of ¥7,710 million. This owed mainly to a ¥8,584 million increase in retained earnings, although there was a ¥965 million decrease in foreign currency translation adjustment due to the appreciation of the yen.

Cash Flows

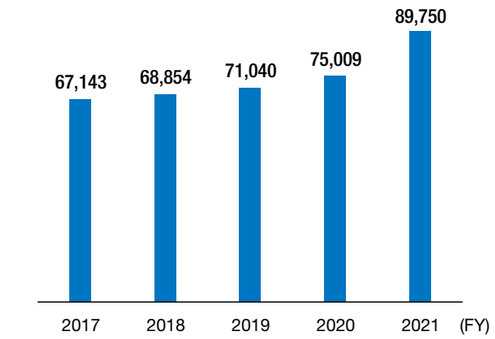
Net cash provided by operating activities was ¥13,943 million, an increase of ¥7,603 million compared with the previous fiscal year. Main factors were ¥13,552 million in income before income taxes, ¥3,706 million in depreciation and amortization, an increase in notes and accounts payable-trade of ¥1,016 million, an increase in notes and accounts receivable-trade of ¥3,559 million, an increase of corporate taxes paid of ¥1,854 million, and an increase in cash outflow of ¥1,767 million in inventories.

Net cash provided by investing activities was ¥3,778 million, which was an increase of ¥3,565 million over the previous fiscal year. Main factors were the purchase of property, plant and equipment and intangible assets of ¥8,687 million, proceeds from sales and redemption of securities of ¥2,000 million, and subsidies received of ¥1,900 million.

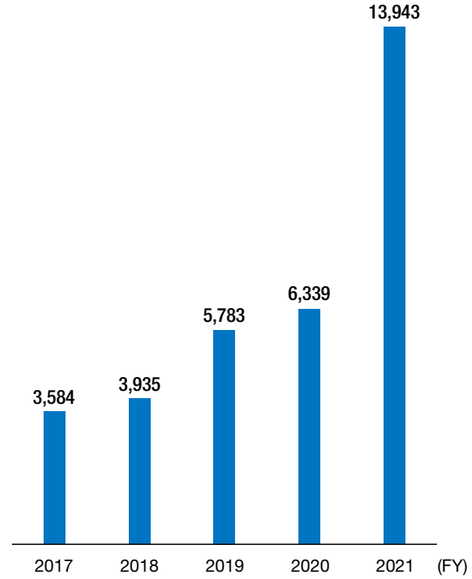
Net cash used in financing activities was ¥1,103 million, a ¥157 million increase compared with the previous fiscal year. This was primarily because of a ¥962 million increase in cash dividends paid.

As a result, the balance of cash and cash equivalents including foreign currency translation adjustments on cash and cash equivalents at the end of the consolidated fiscal year was ¥23,308 million, a year-over-year increase of ¥8,845 million.

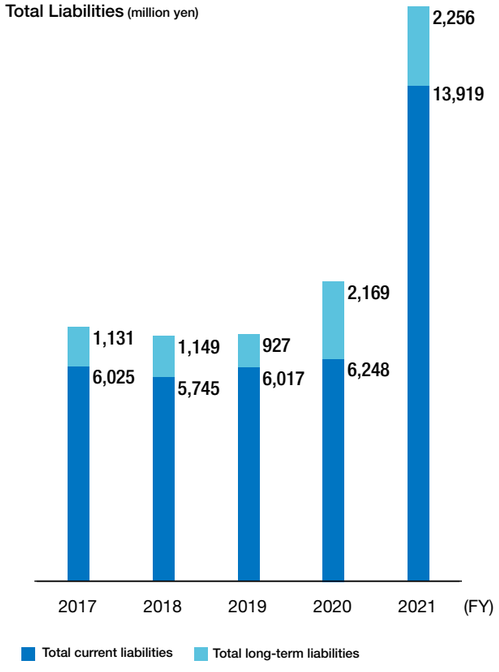
Total Assets (million yen)



Net Cash Provided by Operating Activities (million yen)



Total Liabilities (million yen)



Cash Flow from Business Activities

(million yen)	2017	2018	2019	2020	2021
Net cash provided by operating activities	¥3,584	¥3,935	¥5,783	¥6,339	¥13,934
Net cash provided by (used in) investing activities	13,493	(14,755)	(5,576)	(212)	(3,778)
Net cash provided by (used in) financial activities	(280)	(1,205)	(541)	(946)	(1,103)

Business Risks

With respect to the matters stated in the securities report concerning the status of operations and financial accounting, etc., management is aware of the following principal risks that may materially affect the financial status, business results, and cash flows of the consolidated companies.

It should be noted that references to the future made in this text reflect the judgment of the Group as of the end of the fiscal year under review.

In addition, the explanations of terminology are for investors to use as a reference to understand the information provided in this section. As such, they are based on our judgement and understanding.

1. Markets and Operations

1) R&D activities

Biotechnology-related industries cover a wide range of product fields such as regenerative medicine including gene therapy, as well as research support fields for the purpose of basic research and drug discovery whose direct target markets are universities, public research institutions, companies, and commercial labs, plus an array of other fields covering the environment, energy, food, and information.

Under these circumstances, the Group conducts extensive R&D, which it considers important in maintaining its competitive edge. However, there is no guarantee that R&D will yield adequate results in a timely manner. Clinical development, especially in the field of gene therapy, requires long periods of time, and any delays in R&D could affect the Group's business strategy and performance.

In addition, the business environment surrounding the biotechnology industry has been changing dramatically. Since the business environment of the Group may be significantly affected by new technological innovations and new entrants, there is no guarantee that the R&D currently underway will produce the anticipated results. As a result, the Group could fail to meet its revenue projections.

2) Overseas business

The Group conducts business operations such as R&D, manufacturing, and sales in regions that include North America, Europe, and Asia (mainly China). Significant changes concerning the economic, political, or social climate in these countries and regions, the occurrence of problems concerning international taxation such as transfer price taxation systems may affect the Group's business strategies and performance.

In addition, most of the research reagents that form the product mainstay of the Group are manufactured by the China-based subsidiary Takara Biotechnology (Dalian) Co., Ltd. Changes in the earnings trends of this subsidiary, a suspension of business activities for any reason, or other factors may affect the Group's business strategies and performance. In light of this risk, while giving consideration to balancing efficiency gains and risk reduction, the Group will establish a global, multi-polar manufacturing and R&D system.

3) Competition

The Group holds a unique position in the industry with a stable revenue base, a solid presence in the Asian market, and an extensive line-up of proprietary technologies.

However, manufacturing and sales of reagents and scientific instruments do not require the licensing and approvals needed for medical instruments; in the absence of barriers such as patents, entry into the field is relatively easy. Accordingly, a large number of competitors exist in the market, both in Japan and overseas.

In the field of gene therapy, advances in technology have resulted in the development of therapies that excel in safety and performance, and acquisitions for manufacturing and sales approval have begun overseas. In this burgeoning market, many enterprises are conducting R&D for gene therapy, including biotechnology ventures and big pharma in the U.S. and Europe.

Under such circumstances, the Group is developing technologies and products on a proprietary basis and in cooperation with universities and other outside organizations. If competitors commercialize similar products and fields of technology first, the product development and performance of the Group could be affected. In light of this risk, the Group protects its technology and product developments through intellectual property rights in order to achieve exclusivity or differentiation, and will strive to maintain price competitiveness by promoting cost reductions and strengthening its manufacturing systems.

4) Securing human resources

While the Group is based on R&D, new technological innovation and the emergence of new market players are having a significant influence on the biotechnology industry. Therefore, to maintain its competitive edge, the Group considers it essential to secure outstanding human resources with specialist knowledge and skills. Nevertheless, the Group cannot rule out that it may not be able to secure human resources as planned, or that its personnel may leave the Group. In this event, the Group's business strategy and performance could be affected.

In light of these risks, the Group is making efforts to promote diversity and a healthy work-life balance, while also creating safe and comfortable worksites and working environments.

5) Sales related to initial payments and milestone payments

The Group recognizes initial payments and milestone payments generated under contracts with customers as revenues at the time when the conditions stipulated in individual contracts have been met. However, due to the complexity of contracts, etc., there is a risk of error in the timing of revenue recognition, which may affect the Group's business performance. In light of this risk, the Group is working to enhance its internal controls and is conducting checks through its internal auditing department and finance department.

6) Sales related to contract services

The Group recognizes sales of contract services as revenue as of when they meet the criteria established by the Group. However, due to the complexity of contracts, etc., there is a risk of error in the timing of revenue recognition, which may affect the Group's business performance. In light of this risk, the Group is working to enhance its internal controls and is conducting checks through its internal auditing department and finance department.

2. Finance and Economy

1) Financing

The Group occasionally raises funds to cover rising financing demand for R&D expenditure, capital expenditure, working funds, etc., to accommodate the Group's new business launches and expanding business scale. However, if financing does not proceed as planned, it could affect the Group's business strategies and performance. In light of this risk, the Group works to maintain and strengthen its sound financial position and conducts timely reviews of its financial planning based on the latest information.

2) Exchange rate fluctuation

The translation of costs, income, and trade receivables and payables associated with business undertaken by the Group in denominated foreign currencies is exposed to currency exchange rate fluctuation risk. In light of this risk, the Group enters into forward foreign exchange contracts and other hedging instruments in order to reduce the risk of exchange rate fluctuation.

Additionally, the income, sales, expenses, assets, and other such line items of overseas consolidated subsidiaries are converted into yen for the purpose of creating consolidated financial statements. Consequently, exchange rate fluctuations at the time of account closing may affect the Group's business performance.

3. Finance

1) Impairment of fixed assets

The Group possesses a variety of fixed assets that serve the purposes of our businesses, and intangible assets such as goodwill obtained through corporate acquisitions and technology assets. In the event that production equipment is left idle by a sudden change in the business environment, or due to a decline in utilization rates, or owing to the failure of an acquired business to meet initial projections, or owing to other factors, an impairment loss arises, which may affect the business performance of the Group. In light of this risk, the Group follows up on acquired businesses in order to realize post-acquisition synergies and regularly monitors the macroeconomic environment.

4. Regulatory and Legal Procedures; Natural Disasters

1) Key operational agreements

An outline of the agreements considered crucial to the Group's operations is described below. If these agreements end due to the expiry of the agreement term, cancellation, or some other reason, or if revisions to the agreements are disadvantageous to the Group, it could affect the business strategy and performance of the Group.

(1) Technology In-licensing Agreements

Contracting company	Takara Bio Inc. (the Company)
Counterparty	Yukihiro Nishiyama, M's Science Corporation, Nagoya Industrial Science Research Institute
Contract	Memorandum on Changes to Agreements Concerning Patent Transfer, Joint Application, and Licensing, etc.
Conclusion date	November 26, 2010
Term	From November 26, 2010 to the patent expiration date
Summary	In 2010 Takara Bio took over M's Science Corporation's HF10 business and inherited all of the corporation's rights and obligations pertaining to HF10. This memorandum ensures Takara Bio's partial ownership of patent rights and exclusive use of patents pertaining to HF10. Further, Takara Bio will provide a milestone payment to the Nagoya Industrial Science Research Institute in addition to paying running royalties tied to sales after the approval of HF10.

Note: The current official name of HF10 is canerpaturev and its abbreviation is C-REV.

(2) Technology Out-licensing Agreements

Contracting company	Takara Bio Inc. (the Company)
Counterparty	Otsuka Pharmaceutical Co., Ltd.
Contract	License Agreement for HF10 Development and Sales
Conclusion date	December 15, 2016
Term	From December 15, 2016, until the end of sales, unless terminated due to a reason stipulated in the contract
Summary	Takara Bio and Otsuka Pharmaceutical Co., Ltd. will implement co-development of gene therapies using oncolytic virus HF10 ("the products") in Japan. Takara Bio gives Otsuka Pharmaceutical exclusive rights to commercialize the products for all indications in Japan. In addition to receiving an initial payment and lump sums according to the progress of development, Takara Bio will receive lump sums according to achievement of sales targets following the launch. Further, Takara Bio will manufacture the products for clinical trials and market sales and provide them to Otsuka Pharmaceutical for a fee.

Note: The current official name of HF10 is canerpaturev and its abbreviation is C-REV.

Contracting company	Takara Bio Inc. (the Company)
Counterparty	Otsuka Pharmaceutical Co., Ltd.
Contract	License Agreement for NY-ESO-1·siTCR™ Joint Development and Sales
Conclusion date	April 9, 2018
Term	From April 9, 2018, until the end of sales, unless terminated due to a reason stipulated in the contract
Summary	Takara Bio and Otsuka Pharmaceutical Co., Ltd. will implement co-development of gene therapies (TBI-1301 and TBI-1301-A, hereinafter "the products") using NY-ESO-1·siTCR™ in Japan. Takara Bio gives Otsuka Pharmaceutical exclusive rights to commercialize the products for all indications in Japan and a right of first refusal for nine other Asian countries. In addition to receiving an initial payment and lump sums according to the progress of development, Takara Bio will receive lump sums according to achievement of sales targets as well as running royalties tied to sales after the approval of the products following the launch. Further, Takara Bio will manufacture the products for clinical trials and market sales and provide them to Otsuka Pharmaceutical for a fee.

Contracting company	Takara Bio Inc. (the Company)
Counterparty	Otsuka Pharmaceutical Co., Ltd.
Contract	License Agreement for CD19·CAR Joint Development and Sales
Conclusion date	April 9, 2018
Term	From April 9, 2018 until the end of sales, unless terminated due to a reason stipulated in the contract
Summary	Takara Bio and Otsuka Pharmaceutical Co., Ltd. will implement co-development of gene therapies using CD19·CAR (TBI-1501; hereafter, "the products") in Japan. Takara Bio gives Otsuka Pharmaceutical exclusive rights to commercialize the products for all indications in Japan and a right of first refusal for nine other Asian countries. Takara Bio will receive an initial payment and lump sums according to the progress of development. Further, Takara Bio will manufacture the products for clinical trials and market sales and provide them to Otsuka Pharmaceutical for a fee.

2) Intellectual property rights

In the biotechnology industry, in which the success of the business depends highly on the success of R&D, the Group protects the technologies it develops in-house with patent rights to prevent competitors from imitating them. The Group will continue to place the highest priority on applications for patents based on R&D activities. However, not all applications may be successfully registered, and if a registered patent right becomes invalid or expires, for example, the Group's business strategies and performance may be affected.

Moreover, the Group intends to acquire promising patent rights held by others, or acquire licenses for the patent rights, to enable future expansion of its business. However, these strategies may incur large expenses. In addition, there is a possibility that the Group may not be able to acquire licenses for necessary patent rights held by others, and this could affect the Group's business strategy and performance.

3) Product liability risks

All of the products that the Group handles pose an inherent product liability risk. If any defect is found in a product during its manufacture or sale, or during the clinical trial process; or if a health impairment is caused by any pharmaceutical product, medical devices, regenerative medicine products, or research reagents, investigational drugs used in clinical trials, or specific processed cells, then the Group may be subject to product liability claims, and this could affect the promotion of the Group's business strategies and performance.

In addition, it is usual practice to conduct a voluntary recall when any problem arises with these products in view of the possible physical effects, and any such recall may require time and entail huge expense.

4) Legal regulations

In advancing research and development, the Group is subject to related laws and regulations such as the Law Concerning the Prevention of Radiation Hazards due to Radioisotopes, etc., and the Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (hereinafter "Cartagena Law"), and the Group is committed to observing these laws and regulations. In addition, in the production, sale, and trade of reagents, etc., the Group is required to follow relevant legislations, such as the Poisonous and Deleterious Substances Control Law and the Quarantine Law. However, since reagents are neither pharmaceutical products nor regenerative medical products as defined by the Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (hereinafter "Pharmaceuticals and Medical Devices Law"), this statute and its regulations are not applicable. Nevertheless, if these regulations are tightened or new regulations are introduced following expansion, etc., of the supporting research industry, it could affect the Group's business strategies and performance.

Moreover, gene therapy drugs under development by the Group are subject to related laws and regulations including the Pharmaceutical and Medical Devices Law, the Act on the Safety of Regenerative Medicine, and the Cartagena Law. The purpose of these related laws and regulations is to ensure the quality, effectiveness, and safety of pharmaceutical products, regenerative medical products, quasi-pharmaceutical products, specific processed cells, cosmetics, and medical devices, to the effect that approvals or permits from the relevant authorities are required for commercial activities. Failure to obtain such permits for individual projects being researched or under development by the Group may affect the Group's business strategies.

5) Risks of lawsuits, etc.

The Group is not a party to any important litigation or claim with third parties related to the Group's business. However, litigation may be brought against individual Group companies, and the Group's business strategies and performance may be affected by the litigation itself as well as by its outcome. In light of this risk, the Group works to enhance internal controls and compliance in the pursuit of its business activities in Japan and overseas.

In addition, the Group conducts patent searches through patent offices, etc., in order to prevent in its business development any litigation related to intellectual property rights. The Group is aware of no factual conflict between a product of the Group and a third-party patent. However, it is difficult for R&D companies such as the Group to entirely avoid intellectual property infringement problems. If a pertinent infringement issue arises, the Group may be subject to claims to damages, injunctions, or royalty payments, which may affect the Group's business strategies and performance.

If the Group's business partners or licensors are involved in disputes, the Group may no longer be able to sell the relevant products or may itself become involved in lawsuits. Resolving such a case can be time consuming and costly, which may affect the Group's business strategies and performance.

6) Natural disasters

The Group's business activities may be impeded by natural disasters such as storms, earthquakes, lightning strikes, and floods, by fires or other accidents, or by worldwide pandemics of infectious diseases. To minimize damage suffered in such cases, we conduct inspections and training, and create communication systems and business continuity plans.

7) Extended duration of the influence of the COVID-19 pandemic

The Group expects that the fiscal year ending March 2022 will be impacted by the spread of COVID-19. A continuation of the pandemic for an extended period, with business partners temporarily suspending operations and with delays in the collection of accounts receivable, may affect the Group's business or other performance. In light of this risk, the Group is taking steps to secure sufficient cash on hand.

In addition, Group employees in some locations may be unable to come to work or face other difficulties. In light of this risk, the Group is implementing remote work modes and other work set-ups that enable social distancing.

5. Parent company of Takara Bio

As of March 31, 2021, Takara Holdings is the parent company of Takara Bio, owning 60.93% of the voting rights in the Group. The relationship between Takara Bio and Takara Holdings is as follows.

1) Position of Takara Bio in the Takara Holdings Group (Takara Holdings and its group companies)

The extraordinary general meeting of shareholders of Takara Shuzo Co. Ltd. (hereafter, "Takara Shuzo," now Takara Holdings), held on February 15, 2002, approved the establishment of Takara Shuzo and Takara Bio on April 1, 2002 through a corporate split, with each company becoming a fully owned subsidiary of Takara Holdings. Since then, Takara Holdings decreased the ownership of voting shares in Takara Bio to 60.93% as of March 31, 2020, through a third-party allotment of new shares by private and public offering.

The Takara Holdings Group consists of Takara Holdings, which is a pure holding company, and its 62 group companies (60 subsidiaries and 2 affiliated companies). Within the Group, Takara Bio is positioned as a subsidiary specializing in the biotechnology business, and it promotes the biotechnology business along with its 8 group companies (subsidiaries).

2) Management of Group companies by Takara Holdings

Takara Holdings has established and operates the Takara Holdings Group Company Management Rules from the standpoint of consolidated business management. However, its objective is to maintain the independence and autonomy of Takara Holdings Group companies while seeking to maximize the corporate value of the entire Takara Holdings Group. Takara Bio, too, is subject to these regulations and reports to Takara Holdings on matters resolved by its Board of Directors. However, since prior approval for its Board of Directors' resolutions is not required, Takara Bio is left to operate as an independent business.

Takara Holdings has established a variety of meetings within the Group, of which the following concern Takara Bio.

Meeting name	Participants	Role	Frequency
Group Strategy Meeting	Takara Holdings' directors and executive officers Takara Bio's directors and executive officers Takara Shuzo's directors and executive officers Takara Shuzo International's directors and executive officers	Confirmation of matters related to the entire Group	In principle, once every two months
Bio Business Report Meeting	Takara Holdings' directors Takara Bio's directors and executive officers	Reporting on the status of Takara Bio's activities, etc.	In principle, once a month

The above-mentioned various meetings serve to facilitate the reporting between group companies and do not restrain the autonomy and independence of Takara Bio.

As of the submission date of the annual securities report, the following officers serve concurrently at Takara Holdings and Takara Bio.

Name	Position at Takara Bio	Position at Takara Holdings
Hisashi Ohmiya	Chairman	Chairman
Koichi Nakao	President & CEO	Director

Hisashi Omiya was appointed as a chairman of the Board of Directors of Takara Bio based on its assessment that his experience and knowledge in the management of the Biomedical Group as a director of Takara Shuzo before the establishment of Takara Bio would be of use to the Company. Koichi Nakao was appointed as a director of Takara Holdings from the standpoint of consolidated business management within the holding company structure of Takara Holdings. These decisions were not made with the objective of giving Takara Holdings control over Takara Bio.

A change in the Group management strategy of Takara Holdings could affect the business and performance of the Group.

3) Transactions with the Takara Holdings Group

(1) Real estate lease transactions related to sales sites

Real estate lease transactions exist between the Takara Bio and Takara Shuzo, a subsidiary of Takara Holdings. The real estate lease transactions relating to the lease of sale sites by Takara Bio are as follows. In the event of difficulties in the renewal of these transactions, Group revenue could be affected and relocation expenses incurred until we are able to secure an alternative site.

Property	Use	Lessor	Amount of transaction (Year ended March 31, 2021, Millions of yen)	Transaction terms, etc.
6F and basement Takara Meiji Yasuda Building (Chuo-ku, Tokyo)	Takara Bio, Tokyo Branch	Takara Shuzo	13	Area:140.85m^2 Type of agreement: Lease agreement Rent calculation basis: Market price of land and buildings, etc.

Notes:
1. Amounts do not include consumption taxes, etc.
2. Terms of agreement and method of determining terms of agreement are decided by consultation based on appraisal by real estate appraiser.

(2) Transactions related to use of trademark rights

The Group has concluded trademark licensing agreements with Takara Holdings with regard to the trademarks it uses which are owned and controlled by Takara Holdings, and makes usage payments per trademark. As of March 31, 2021, Takara Bio had licenses for the use of 64 registered trademarks and a pending trademark in Japan and overseas.

In the event that the Group is unable to obtain licenses for the use of trademarks from Takara Holdings, it might affect our business strategies and performance.

Company name (Location)	Details of transaction	Amount of transaction (Year ended March 31, 2021, Millions of yen)	Terms of transaction, etc.
Takara Holdings Inc. (Shimogyo-ku, Kyoto)	License for use of trademarks	6	Type of agreement: License agreement for use of trademarks (concluded on March 29, 2004) License fee calculation basis: Cost of trademark right application, registration, and future maintenance and management Monthly license fee per trademark, country, and category: ¥8,500 for registered trademarks, ¥1,700 for pending trademarks (fees excluding consumption taxes, etc.)

Note: Amounts do not include consumption taxes, etc.

(3) Transactions related to outsourcing of computer-related services

Takara Bio has concluded agreements with Takara Holdings on the contracting of computer-related services and the lease of equipment.

In the event of difficulties in the renewal of these transactions, it might affect the Group's business strategies and performance.

Company name (Location)	Details of transaction	Amount of transaction (Year ended March 31, 2021, Millions of yen)	Terms of transaction, etc.
Takara Holdings Inc. (Shimogyo-ku, Kyoto)	Contracting of computer-related services and leasing of equipment, etc.	407	Type of agreement: Basic agreement on contracting of computer-related services and leasing of equipment Service details: Support for accounting system operations, support for client server operation, lease of PCs, purchase of supplies, and other

Note: Amounts do not include consumption taxes, etc.

(4) Other

The Group purchases packaging materials from Takara Holdings Group companies (excluding Takara Bio Group companies). In the event of difficulties in the renewal of these transactions, it might affect the Group's strategies and performance.

Investor Information

As of March 31, 2021

Corporate Data

Trade Name	Takara Bio Inc.
Head Office	7-4-38 Nojihigashi, Kusatsu, Shiga 525-0058, Japan
Telephone	+81-77-565-6920 PR and IR Department: +81-77-565-6970
Established	April 1, 2002
Issued Capital	¥14,965,828,496
Lines of Business	Production and sales of research reagents, scientific instruments and others, CDMO business, and gene therapy business
Number of Employees of Takara Bio Group	1,539 (consolidated)
URL	www.takara-bio.com

Main Offices

Headquarters	7-4-38 Nojihigashi, Kusatsu, Shiga 525-0058, Japan
Kusatsu Office	7-2-62 Nojihigashi, Kusatsu, Shiga 525-0058, Japan
Tokyo Branch	2-15-10 Nihonbashi, Chuo-ku, Tokyo 103-8232, Japan

Consolidated Subsidiaries	Location	Issued Capital and Subscription	Line of Business
Takara Biotechnology (Dalian) Co., Ltd.	Dalian, People's Republic of China	¥2,350 million	Development, production and inter-group sales of research reagents, and related contract services
Takara Korea Biomedical Inc.	Seoul, Korea	₩3,860 million	Sales of research reagents and scientific instruments
Takara Biomedical Technology (Beijing) Co., Ltd.	Beijing, People's Republic of China	¥1,330 million	Sales of research reagents and scientific instruments
DSS Takara Bio India Pvt. Ltd.	New Delhi, India	₹110 million	Production and sales of research reagents
Takara Bio USA Holdings Inc.	Mountain View, U.S.A.	$70,857 thousand	Subsidiary management
Takara Bio USA, Inc.	Mountain View, U.S.A.	$83 thousand	Development, production and sales of research reagents and scientific instruments
Takara Bio Europe S.A.S.	Saint-Germain-en-Laye, France	€891 thousand	Sales of research reagents and scientific instruments
Takara Bio Europe AB	Gothenburg, Sweden	Skr2,222 thousand	Production and sales of research reagents, and related contract services
Takara Bio UK Ltd.	London, U.K.	£100 thousand	Sales of research reagents and scientific instruments

Investor Information

Common Shares	
Authorized	400,000,000 shares
Issued	120,415,600 shares
Total Number of Shareholders	46,323
Stock Listing	First Section of Tokyo Stock Exchange (securities code number: 4974)
Fiscal Year	From April 1 to March 31 of the following year
Annual Meeting of Shareholders	Every June
Record Date	Dividends March 31 Interim dividends September 30 Other record dates will be posted in advance if necessary
Share Unit Number	100 shares

Distribution of Shareholders

Major Shareholders

Name	Number of Shares Held	Percentage of Issued Shares
Takara Holdings, Inc.	73,350,000	60.91%
The Master Trust Bank of Japan, Ltd. (trust account)	4,012,100	3.33%
Custody Bank of Japan, Ltd. (trust account)	2,592,700	2.15%
THE BANK OF NEW YORK, NON-TREATY JASDEC ACCOUNT	1,400,000	1.16%
J.P. MORGAN BANK LUXEMBOURG S.A. 381572	1,088,300	0.90%
Custody Bank of Japan, Ltd. (trust account 5)	802,200	0.67%
Custody Bank of Japan, Ltd. (trust account 6)	711,400	0.59%
J.P. MORGAN BANK LUXEMBOURG S.A. 384513	698,400	0.58%
Custody Bank of Japan, Ltd. (trust account 1)	632,400	0.53%
JP MORGAN CHASE BANK 385781	598,613	0.50%

TAKARA BIO INC.

7-4-38 Nojihigashi, Kusatsu, Shiga 525-0058, Japan
URL: https://www.takara-bio.com/

Inquiries

PR & IR Department, Takara Bio Inc.
e-mail: bio-ir@takara-bio.co.jp

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