TAKARA BIO REPORT 2020

TAKARA BIO INC.

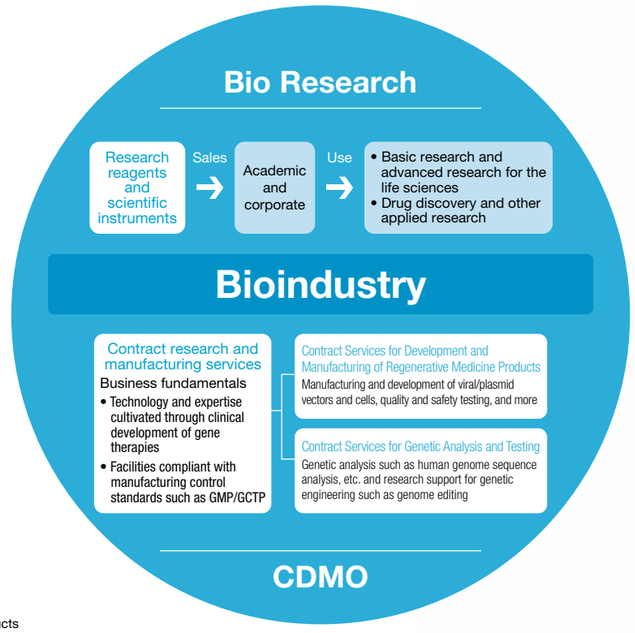
THE BIOTECHNOLOGY COMPANY™

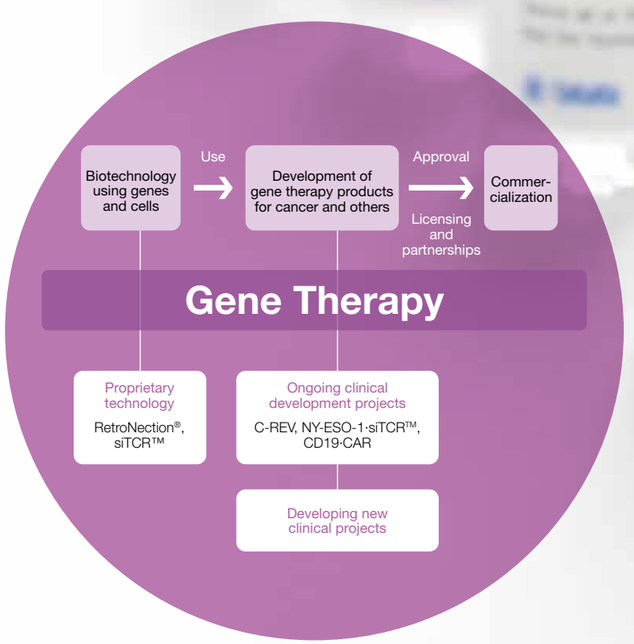
Corporate Philosophy

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

Takara Bio aims to be a drug discovery company that continually creates new modalities (treatments) by developing platform technology for biologics discovery 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.

*Contract services for development and manufacturing of regenerative medicine products





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
- Began genetic testing services

2000
- Launched full-scale genetic analysis services

2006
- Began next-generation sequence analysis services

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
- Launched direct PCR kits to detect the novel coronavirus

Gene Therapy

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

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

Company

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

1970
- Developed the world's first large-scale production technology for Bunashimeji mushrooms

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)

2001
- Established Mizuho Norin Co., Ltd. (transferred in 2019)

2002
- **Established Takara Bio Inc.**
  Took over Takara Shuzo Co.'s biotechnology business and established Takara Bio Inc. in the city of Otsu, Shiga
- Established Takara Bio Farming Center Inc. (transferred in 2019)

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.)

2007
- Established KINOKO CENTER KIN INC. (transferred in 2019)

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

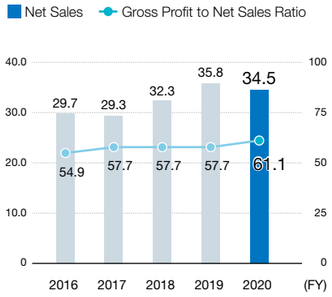
2017
- Acquired Rubicon Genomics, Inc. and WaferGen Bio-systems, Inc. (later merged into Takara Bio USA, Inc.)

2019
- Transferred functional food business and mushroom business

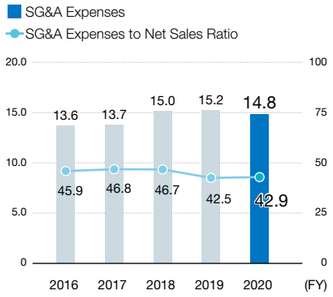
2020
- Launched the Center for Gene and Cell Processing II

Financial (Consolidated) Highlights

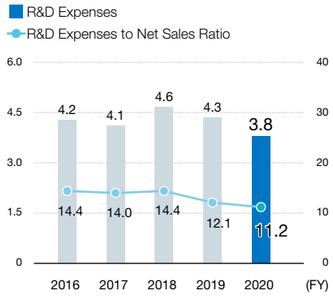
Net Sales (billion yen) / Gross Profit to Net Sales Ratio (%)



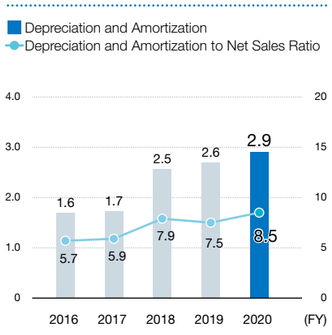
SG&A Expenses (billion yen) /SG&A Expenses to Net Sales Ratio (%)



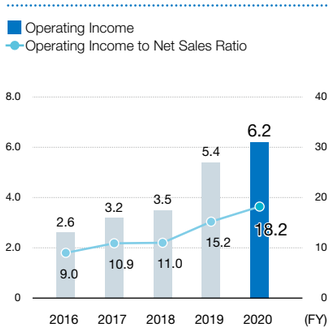
R&D Expenses (billion yen) / R&D Expenses to Net Sales Ratio (%)



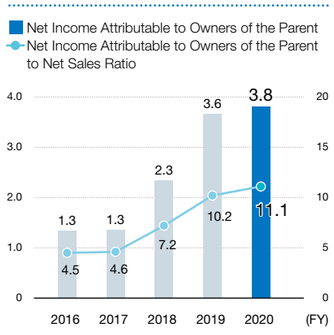
Depreciation and Amortization (billion yen) / Depreciation and Amortization to Net Sales Ratio (%)



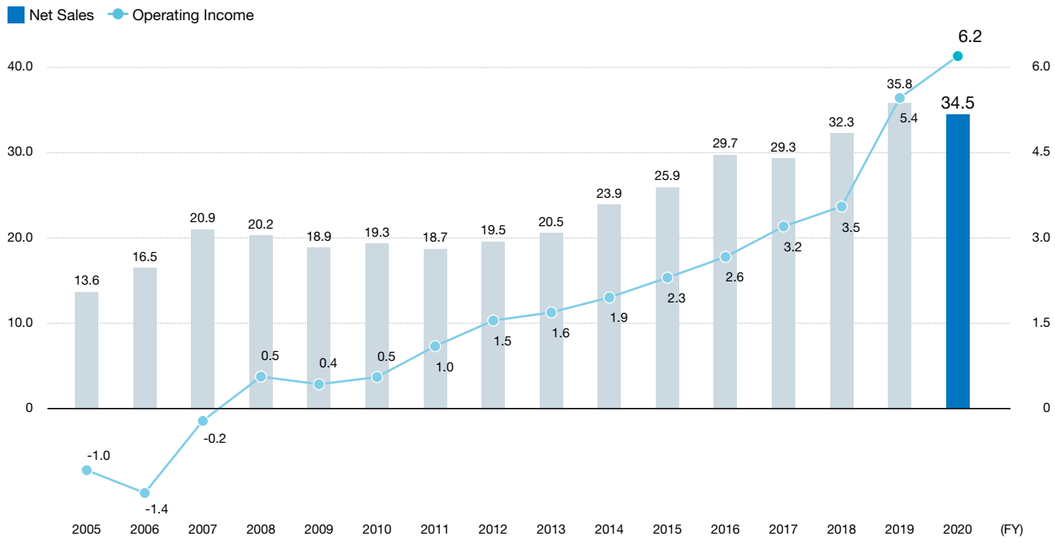
Operating Income (billion yen) / Operating Income to Net Sales Ratio (%)



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

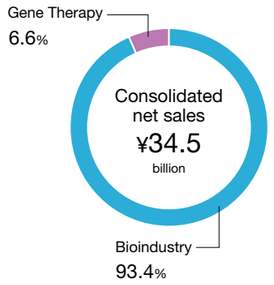


Financial Results (billion yen)

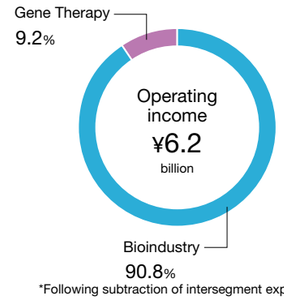


Note: FY2020 in this report refers to the fiscal year ended March 2020

FY2020 Sales Composition

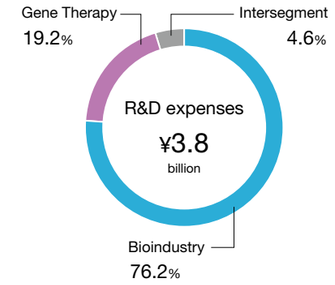


Operating Income Composition*

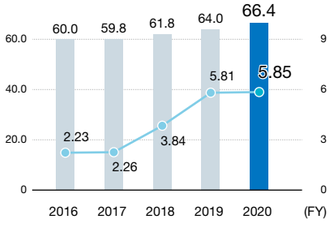


*Following subtraction of intersegment expenses

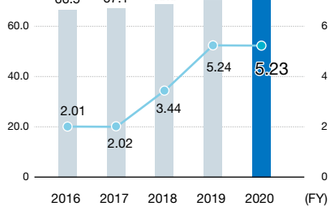
R&D Expenses Composition



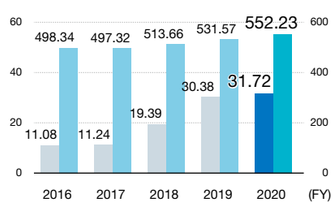
Equity (billion yen) /ROE (%)



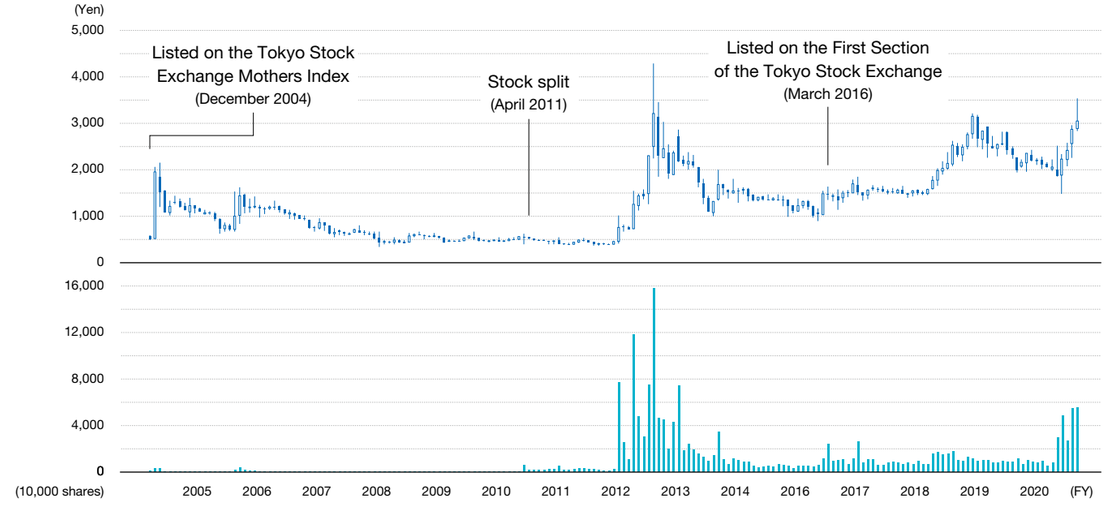
Total Net Assets (billion yen) /ROA (%)



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



Share Values (above) and Turnover (below)



- Period: December 2004–June 2020
- Number of shares listed are those post-stock split adjustment

Koichi Nakao
President

We aim to be a drug discovery company that creates new modalities with platform technology for biologics discovery through our reagents, instruments, and CDMO.

In this fiscal year, we launched a new three-year Medium-Term Management Plan 2023 and a Long-Term Management Plan 2026. We will be intensifying our efforts going forward.

Reflections on FY2020 Business Performance and the Medium-Term Management Plan 2020

Operating income has increased year over year for the past 11 years

I would like to express my deepest sympathies to all those affected by the novel coronavirus disease (COVID-19).

Fiscal 2020 was the final year of the Takara Bio Medium-Term Management Plan 2020. We worked toward our overall objective of enhancing Takara Bio's standing as a global enterprise and regenerative medicine products company and achieving prodigious growth.

Consequently, even though we increased net sales for the consolidated fiscal year in our core businesses of research reagents and contract services over the previous year and received remuneration for fees involved in the joint development and exclusive sales agreement for the NY-ESO-1·siTCR™ gene therapy product and CD19·CAR gene therapy product, revenue decreased to ¥34,565 million (96.4% of the previous year) due to other factors such as transferring our AgriBio Business in the last fiscal year.

The cost of sales was ¥13,459 million (88.8% of the previous year) due to a decrease in sales as well as other factors such as changes in product composition, making gross profit ¥21,105 million (102.0% of the previous year). Selling and general administrative expenses were ¥14,830 million (97.4% of the previous year) due to a decrease in R&D expenses, among other factors, and operating income increased to ¥6,274 million (114.8% of the previous year). Following growth in operating income, ordinary income increased to ¥6,347 million (112.1% of the previous year), income before income taxes to ¥5,433 million (112.7% of the previous year), and net income attributable to owners of the parent to ¥3,819 million (104.4% of the previous year).

The quantitative targets for the final fiscal year set at the launch of the Medium-Term Management Plan 2020 were sales of ¥38.5 billion and operating income of ¥4 billion. At the end of the three-year plan period, although sales did not reach the target for the final fiscal year due to factors such as the transfer of our AgriBio Business, operating income substantially exceeded the target due to growth in foreign sales of research reagents, expansion of our CDMO business, and receipt of remuneration for projects in our gene therapy business.

Bioindustry Business

In our core businesses, we saw robust performance in research reagents and immense growth in revenue from contract services

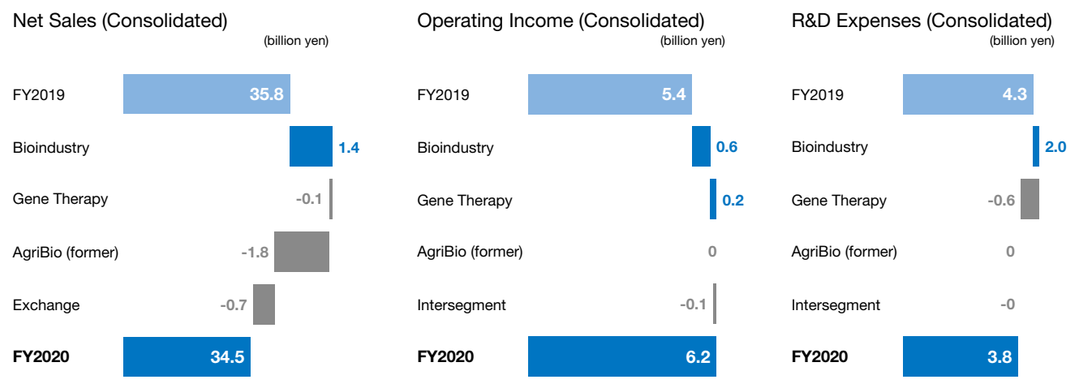
Takara Bio offers a wide variety of products and services for basic research and industrial applications in the life sciences to universities and companies all over the world.

In fiscal 2020, we launched full-scale operations at the Center for Gene and Cell Processing II, a research and manufacturing facility for regenerative medicine products, with the aim of expanding our CDMO business. We also made efforts to combat the ongoing COVID-19 pandemic by developing, manufacturing, and selling reagents for PCR tests and participating in vaccine development led by a group at Osaka University, etc.

Gene Therapy Business

We are making process in clinical development of gene therapies in pursuit of early commercialization

In fiscal 2020, a phase I/II clinical trial in Japan of our NY-ESO-1·siTCR™ gene therapy product for synovial sarcoma completed the treatment stage with all planned patients treated and currently in the observation stage. It is now planned to apply for manufacturing and marketing approval of this product. A Japanese phase I/II trial of CD19·CAR gene therapy in adult acute lymphoblastic leukemia and a Japanese phase I trial of the oncolytic virus C-REV in pancreatic cancer are also underway.



Development status of clinical development projects (as of September 2020)

Project / Development Product			Target disease	Development stage			
				Pre-clinical	Clinical trials	IND	Approval
Engineered T Cell Therapy	NY-ESO-1·siTCR™ (TBI-1301)	Japan*1	Synovial sarcoma		Phase I/II in progress	2020 (estimated)	
		Canada	Solid tumor		Investigator-initiated clinical trial in progress		
	CD19·CAR (TBI-1501)	Japan*1	Adult ALL*3		Phase I/II in progress		
	CD19·JAK/STAT·CAR (TBI-2001)	Canada	Blood cancer				
	CEA·GITR·CAR (TBI-2002)	Japan	Solid tumor				
Oncolytic Virus	C-REV (TBI-1401) INN*4: canerpaturev	Japan*1	Pancreatic cancer		Phase I in progress		
		Korea*2	All diseases				
		U.S.	Melanoma		Investigator-initiated clinical trial in progress		

*1 In partnership with Otsuka Pharmaceutical Co., Ltd. *2 In partnership with Dong-A ST Co., Ltd. *3 Acute lymphoblastic leukemia *4 International nonproprietary name

Shareholder Return

An increase on dividends for the eighth consecutive term

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 our businesses.

In fiscal 2020, Takara Bio paid year-end dividends of ¥8 per share, an increase of ¥1 over the previous year.

Outlook for FY2021 Business Performance

Kick-start toward achieving goals set forth in the Medium-Term Management Plan 2023

In fiscal 2021, we project that both sales and profit will decrease with maximum consideration to the negative impacts of a decline in research activity by our customer base of researchers due to the COVID-19 pandemic. We project that sales will fall to ¥33,800 million (97.8% of the previous year), operating income to ¥4,500 million (71.7% of the previous year), ordinary income to ¥4,600 million (72.5% of the previous year), and net income attributable to owners of the parent to ¥2,600 million (68.1% of the previous year). However, we anticipate that these effects will be temporary as the life sciences industry is expanding on a global scale. There is also a possibility that figures will improve because we have not considered performance-boosting factors such as increases in sales from new PCR test kit products or contract manufacturing of DNA vaccines in our forecasts. If circumstances change in a way that warrants revision to our performance forecast, we will promptly publish that information.*1

Formulated Long-Term Management Plan 2026 and Medium-Term Management Plan 2023

We have created a six-year Long-Term Management Plan 2026 to define what we aim to be as a company in the near future. We simultaneously formulated a Medium-Term Management Plan 2023 as the plan for the first three years of this period that ends in fiscal 2023.

Takara Bio Group continues to improve its business performance, including achieving an increase in profit for 11 consecutive years, through efforts such as overseas development of research reagents, expansion of our CDMO business, and advances in gene therapy projects. However, the business environment in which the Group operates has become increasingly challenging as a result of major shifts both domestically and internationally, shaped by events such as the global COVID-19 pandemic, prolonged trade friction between the United States and China, and Brexit.

In the area of drug discovery for regenerative medicine products such as gene therapies, which is a major area of emphasis for Takara Bio Group, development and commercialization of various modalities (treatments) is advancing and competition is intensifying globally between companies of all sizes, from small biotech ventures to huge pharmaceutical companies.

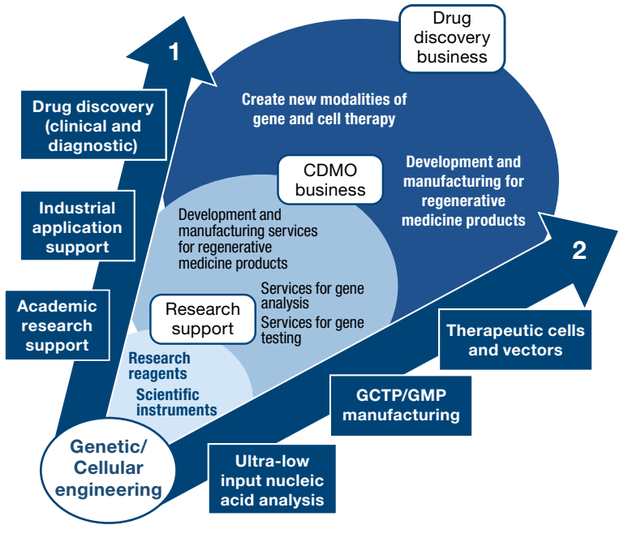
In addition, there has been increased social interest in corporate activities to promote sustainability, for example, by tackling environmental and social problems, and there is now an expectation that companies should actively work to solve social problems in addition to generating good performance and financial results.

As we navigate this environment, we at Takara Bio Group will look to our corporate philosophy of "Contributing to the health of humankind through the development of revolutionary biotechnologies such as gene therapy" and aim to be a drug discovery company*2 that continually creates new modalities by developing platform technology for biologics discovery through our core businesses of research reagents/scientific instruments and CDMO services.

We will keep contributing to society by continuing to create new value and achieving sustainable growth through proactive business activities.

*2 Takara Bio Group defines this business model not as a fully integrated pharmaceutical company capable of taking a drug through the full product lifecycle from R&D to manufacturing to marketing completely in-house, but rather as a company that profits from activities such as out-licensing newly developed modalities.

Vision of Long-Term Management Plan 2026 (FY2021-2026)



1. Business area expansion
   Expand the business from research support areas such as academia to clinically relevant fields, and even drug discovery
2. Development of new technology
   Develop platform technologies for drug discovery via developing new products such as research agents, and new products for our CDMO business

Overall objectives

Under our corporate philosophy of "Contributing to the health of humankind through the development of revolutionary biotechnologies such as gene therapy," the Group has a figure aimed in fiscal 2026 to achieve sustainable growth.

Vision (ideal)

Through the "research reagents and scientific instruments businesses" and "CDMO business," the Group promotes the development of bio-drug discovery platform technologies and aims to be a drug discovery company that continuously creates new modalities.

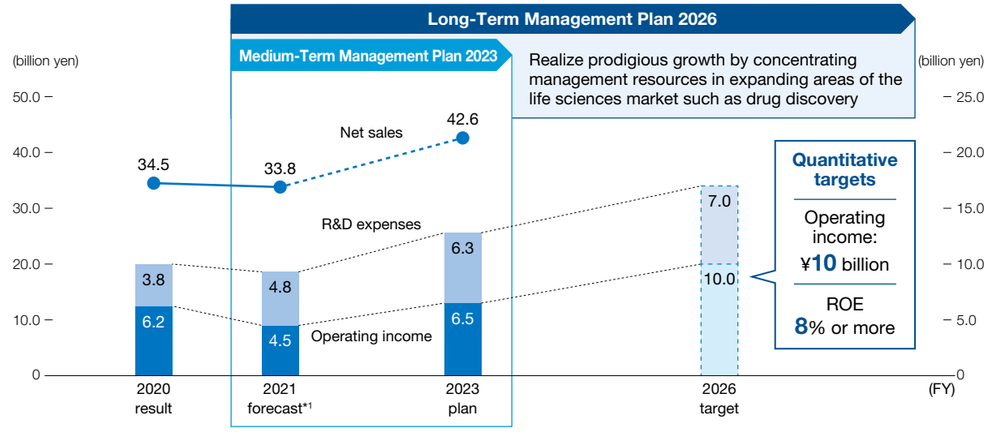
Quantitative targets (FY2026)

Operating income ¥10 billion

ROE 8 % or more

Medium-Term Management Plan 2023 (FY2021-2023)

Overall objective	To carry out strategies to grow business and strengthen our business base while investing proactively in R&D and building a foundation for growth over a three-year period in pursuit of realizing our Long-Term Management Vision 2026 (operating income of ¥10 billion).
Quantitative targets	FY2023 Operating income ¥6.5 billion ROE 6 % or more
Business strategies	• Continue to grow our core businesses of research reagents/scientific instruments and CDMO services • Accelerate formation of drug discovery alliances and create new clinical projects in pursuit of prodigious near-future growth • Accelerate entry into growing global markets and expand our business areas • Abolish the business division structure and restructure the company organization by integrating divisions to accelerate growth
Strategies to strengthen our business base	• Maximize proactive growth investments and shareholder return and increase ROE • Foster employees, organizations, and a work environment that support growth • Strengthen our technology and R&D bases • Build new profit bases by improving productivity • Create social value by practicing our corporate philosophy



*1 The fiscal 2021 performance forecasts in this report are based on figures released on May 14, 2020. Please see the Takara Bio website for the latest performance forecasts.

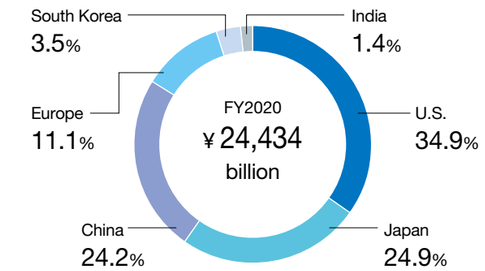
Business Strategy 1

Putting effort into expanding our research reagents business

We are putting vigorous effort into the development, manufacturing, and sales of research reagents.

Our aims are to optimize development themes within the Group, optimize and maximize the efficiency of manufacturing systems, continually reduce costs, and enhance quality control. We will also build a “glocal” sales system that considers local characteristics.

Sales by geographic segment

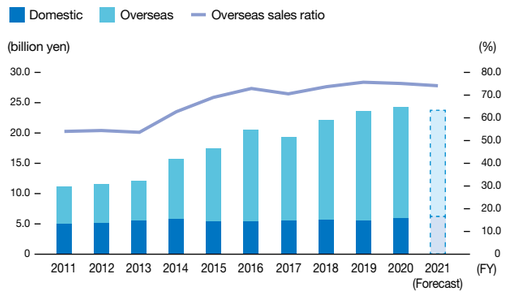


Business Strategy 2

Improving and expanding the main offices of our U.S. subsidiary

We will move the main offices for Takara Bio USA, which develops research reagents and scientific instruments and is in charge of North American sales, from Mountain View, California to San Jose, and will take this opportunity to improve and expand the facilities. San Jose is at the center of Silicon Valley and is home to a global life sciences industry cluster of many universities and high-tech companies that conduct advanced IT and biotechnology research. These new offices will also be a critical hub for sales activities and information gathering. They are scheduled to open for business in August 2021.

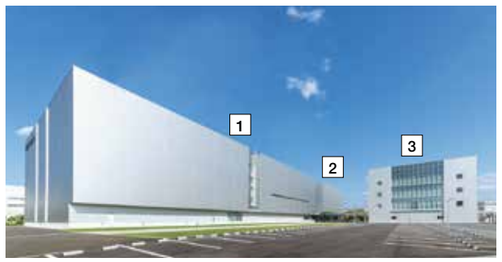
Changes in research reagent sales and overseas sales ratio



Launched full scale operations at the Center for Gene and Cell Processing II

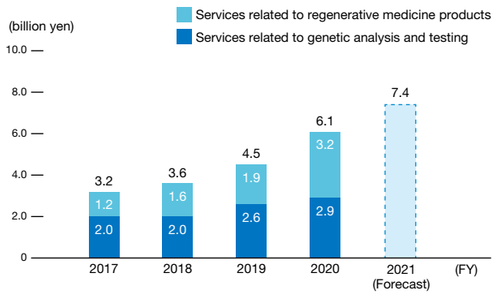
We completed construction of the Center for Gene and Cell Processing II, a research and manufacturing facility for regenerative medicine products near our headquarters in Kusatsu, Shiga Prefecture, and launched full-scale operations there in January 2020. The new facility has over twice the total floor space of the previous facility (14,500 m^2) and complies with manufacturing and quality control standards for pharmaceutical products and regenerative medicine products, such as GMP and GCTP.

Going forward, we plan to apply for accreditation of specific processed cells stipulated in the Act on the Safety of Regenerative Medicine and quality management system for ISO 9001, etc. We aim to utilize this remarkably increased manufacturing capacity to further expand and grow our CDMO business.



1 Center for Gene and Cell Processing II (new facility)
2 Center for Gene and Cell Processing
3 Main building

Changes in CDMO business performance



*The fiscal 2021 performance forecasts in this report are based on figures released on May 14, 2020. Please see the Takara Bio website for the latest performance forecasts.

Business Strategy 3

Business efforts related to COVID-19

We are utilizing our technology and expertise built through research and development of research reagents and gene therapy products to help stop the spread of COVID-19.

Supplying research reagents for PCR testing

We are continuing to supply research reagents on schedule to universities, public research institutions, and pharmaceutical companies around the world conducting life sciences research. Everyone across Takara Bio is also working hard to ensure there are no delays in delivering our CDMO services.

In particular, we consider it our responsibility as one of the few domestic manufacturers of reagents for PCR testing for COVID-19 to ensure an adequate supply of those reagents in Japan.

We have also attempted to expand and strengthen the PCR testing system: on May 1, we released a new rapid and easy-to-use PCR kit called the SARS-CoV-2 Direct Detection RT-qPCR Kit that does not require preprocessing by purification of viral RNA from the specimen and reduces reaction time to less than one hour.

Features of the SARS-CoV-2 Direct Detection RT-qPCR Kit

- Direct test kit that does not require an RNA extraction and purification kit
- Easy to use and takes less than one hour from specimen preprocessing to completion of PCR
- Systems capable of manufacturing and shipping enough product for two million reactions per month

SARS-CoV-2 Direct Detection RT-qPCR Kit

Cooperation in the development of a preventive DNA vaccine

We are maximizing the impact of our technology and expertise built through clinical development and manufacturing of gene therapy products to collaborate in the development of a preventive DNA vaccine against COVID-19 as part of a group led by Osaka University and AnGes, Inc. Possessing the necessary plasmid DNA manufacturing technology and facilities, Takara Bio is undertaking to construct and manufacture a DNA vaccine.

Features of DNA vaccines

- Safe, with absolutely no pathogenic potential unlike an attenuated vaccine because it is manufactured based on the genetic information of the virus without using any dangerous pathogens at all
- Induce immunity by stimulating production of antibodies against pathogenic proteins produced in the body by vaccination
- Can be quickly mass-produced by culturing E. coli

DNA vaccines for animal studies
(photo: provided by Osaka University)

Bioindustry Business

Takara Bio offers research reagents, scientific instruments, and CDMO services for academic and corporate life sciences research and development.

Research Reagents and Scientific Instruments

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

Our TaKaRa® brand was the first brand in Japan to develop and market restriction enzymes, and commenced its research reagents business in 1979. Since then, it has expanded into the production of reagents for genetic, protein and cellular engineering. In 1988, it became the first brand in Japan to exclusively market PCR systems (instrument and reagents as a unit), and boasts an extensive range of products across the entire bioresearch spectrum.

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 cDNA 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 successfully developed an ultra-low input genetic analysis system for single-cell analysis and have started selling that system.

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

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

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

TaKaRa®'s PCR machine, Thermal Cycler Dice® Real Time System III

CDMO Services

Our CDMO services provide a seamless package of regenerative medicine development support services and genetic testing support services such as genome sequence and genetic analysis for regenerative medicine products.

1. Contract Service for Developing Regenerative Medicine Products

Our contract services include not only manufacturing of viral vectors and gene-transduced cells, which are the key to gene therapy, but also related services such as quality and safety testing and cell banking.

2. Contract Services for Supporting Genetic Analysis and Testing

In addition to genetic testing support services that utilize next-generation sequencing, such as human genome sequence analysis, comprehensive analysis of cancer-related genes, and intestinal flora analysis, we offer support services for advanced genetic engineering research such as genome editing using the latest technologies and equipment.

Our CDMO services at work

Future Initiatives

Research reagents

- Improve development efficiency by optimizing development themes across our Japanese, U.S., and Chinese hubs.
- Optimize and maximize efficiency across the entire Group by dividing and restructuring our manufacturing systems across Japan, the U.S., China, and Europe.
- Increase our competitiveness in terms of value and quality through such methods as continual reductions in costs and expanding the scope of quality management system certification.
- Build a "glocal" sales strategy that considers local characteristics.

Scientific instruments

- Intensify development of viral tests and other PCR-related products for industrial and medical fields and further expand into the veterinary/livestock and environmental fields.
- Increase sales by expanding into new applications such as single-cell analysis instruments and use these products to develop new CDMO service offerings as well.
- Develop new products with high added value by pairing instruments and instrument-specific reagents as systems.

CDMO services

- Expand business by taking advantage of our markedly increased manufacturing capacity for regenerative medicine products generated by growth and expansion of the Center for Gene and Cell Processing.
- Improve technology for viral vector manufacturing and gene transduction and strengthen our GMP manufacturing system in the area of regenerative medicine products.
- Enter the clinical field and increase our capacity to handle large-scale genome analysis projects in the area of genetic analysis and genetic testing.

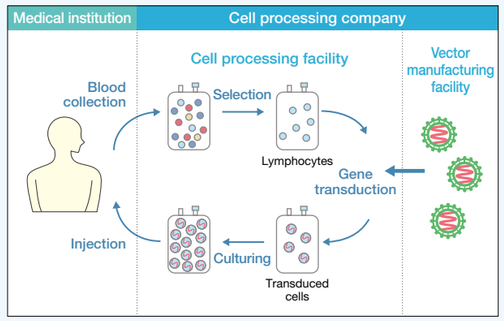
TOPICS

What is a Contract Development and Manufacturing Organization (CDMO)?

A CDMO is an organization that provides development and manufacturing services on a contract basis. In the field of regenerative medicine, where Takara Bio is focused, there is a wide variety of products and thus clients need manufacturing processes and quality control tailored to their individual product. This requires specialized facilities and equipment as well as complex and advanced technology. For these reasons, development and manufacturing of regenerative medicine products are often contracted to CDMOs starting early in development.

We aim to maintain our position as a leading Japanese CDMO for regenerative medicine products by applying the technology and expertise we have cultivated through developing gene therapies in-house, as well as by building facilities and quality control systems that meet domestic and international manufacturing control standards.

Manufacturing of transduced cells (example of a CDMO service)



Gene Therapy Business

We aim to continually create new gene and cell therapy modalities by developing platform technology for biologics discovery through our business that support research.

Thus far, we have formed drug discovery alliances with pharmaceutical companies by using our proprietary platform technology for biologics discovery such as the RetroNectin® method and siTCR™ technology to conduct various clinical development projects inside and outside Japan, including engineered T cell therapies such as NY-ESO-1·siTCR™ gene therapy and CD19·CAR gene therapy as well as the oncolytic virus C-REV. We will continue to conduct clinical development projects through these alliances and maximize the value of ongoing projects.

Engineered T cell therapy

siTCR™ gene therapy

T cell receptor (TCR) gene therapies involve collecting immune cells called T cells from a cancer patient, transducing TCR genes that have the ability to recognize cancer cells into those T cells, expanding the cells, and administering the cells back into the patient. These transduced T cells gain the ability to specifically recognize and attack cancer cells, and are thus utilized in cancer therapy. We are currently working on a gene therapy project using NY-ESO-1·siTCR™ for synovial sarcoma.

CAR gene therapy

Chimeric antigen receptors (CARs) are made by artificially combining T cell surface antibodies that recognize cancer cells with cytotoxic components derived from T cell receptors. CAR gene therapies involve infusion of T cells transduced with CAR genes into the patient, allowing these genetically engineered T cells to specifically recognize and attack cancer cells. We are currently working on a gene therapy project using CD19·CAR for adult acute lymphoblastic leukemia.

Oncolytic virus

Canerpaturev (C-REV)

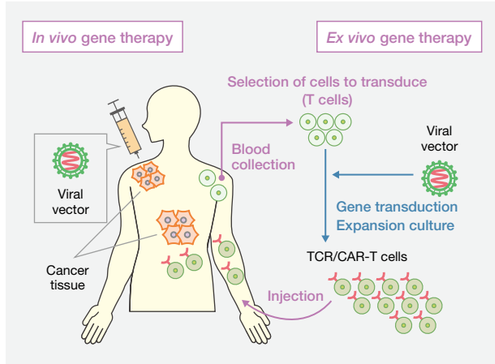
C-REV is an attenuated strain of the herpes simplex virus type 1 (HSV-1) that exhibits antitumor activity upon local injection into a tumor due to tumor lysis. Treatment with C-REV also strengthens general immunity against cancer cells, and shows promise for producing an antitumor effect even in tumors not directly injected with C-REV. This type of virus is called an oncolytic virus. These viruses selectively replicate and destroy tumor tissue without excessively damaging normal tissue, and are being developed as new treatment agents for cancers. We are currently working on a clinical development project using C-REV for pancreatic cancer.

New clinical development projects

We are putting effort toward starting early clinical trials for new clinical development projects. In our *ex vivo* gene therapy project, we are developing platform technology to overcome technical challenges with existing CARs and TCRs. We are also preparing to conduct early clinical trials in new CAR gene therapy projects.

In our *in vivo* gene therapy project, we are aiming to develop new vectors that are highly effective and safe, and to create new clinical projects using those vectors.

In vivo and *ex vivo* gene therapy



Future Initiatives

(1) Drug discovery alliances

- Steadily progress clinical development alongside partner companies for our NY-ESO-1·siTCR™ (TBI-1301), C-REV (TBI-1401), and CD19·CAR (TBI-1501) projects and aim for early launch to market while accelerating formation of new international partnerships and out-licensing activities

(2) New clinical development projects

- Quickly start clinical trials for our CD19·JAK/STAT·CAR (TBI-2001) and CEA·GITR·CAR (TBI-2002) projects and develop multiple new gene therapy projects
- Develop CARs and siTCR™ therapies effective against solid cancers, not just blood cancers, for *ex vivo* gene therapy
- Develop new viral vectors that are better tolerated by patients for *in vivo* gene therapy

TOPICS

Proprietary technology advancing gene therapy: RetroNectin® method

The RetroNectin® method was jointly developed by Takara Bio and Indiana University in the U.S. in 1995. It enables high-efficiency gene transduction into blood cells such as hematopoietic stem cells, which had been considered extremely challenging up to that point. This technology was a breakthrough that advanced the field of gene therapy, and the RetroNectin® method is now a critical platform technology for gene therapy. Cancer immunotherapies such as CAR-T gene therapy have attracted interest in recent years due to their high efficacy. These therapies involve collecting immune cells from a cancer patient, transducing genes that give instructions to recognize and attack cancer cells into those cells, expanding the cells, and administering the transduced cells back into the patient. Using the RetroNectin® method in this process enables efficient production of large quantities of transduced cells.

RetroNectin®

NY-ESO-1·siTCR™ gene therapy product designated as an Orphan Regenerative Medicine

In June 2020, the Japanese Minister of Health, Labour and Welfare granted Orphan Regenerative Medicine designation for synovial sarcoma to NY-ESO-1·siTCR™ (TBI-1301), a gene therapy product that Takara Bio is developing in Japan as a joint project with Otsuka Pharmaceutical. The Orphan Regenerative Medicine designation, as defined in the Pharmaceutical and Medical Device Act, can be granted to products targeting diseases that affect fewer than 50,000 people in Japan, and whose research and development in Japan have not progressed sufficiently due to the small patient population, despite there being a high medical need for the product. The program is designed to support and promote development to ensure that safe and high-quality therapies are delivered to patients as quickly as possible. Recipients of this designation can obtain advice, counseling, and priority review to aid with early approval of their product, and also qualify for assistive measures such as favorable tax treatment and an extended re-examination period.

As a leading company in PCR products, we will continue to provide a steady supply of PCR products for novel coronavirus testing and other applications.

Tsuyoshi Miyamura
Director and General Manager of Marketing

PCR tests have been attracting great interest as COVID-19 spreads across the globe. PCR tests detect the presence of genes (genetic information) from a virus or other such source. The result comes back positive if a viral gene is present, and negative if not. However, it is not possible to directly detect the virus in a specimen even if present because there are extremely few copies of viral genes. That is why the tests employ a gene-amplifying technology called PCR.

PCR is a technology that selectively amplifies genes artificially in a test tube. When performed using a special instrument and reagent, PCR can increase the number of copies of a gene by about one million times in one to two hours.

Takara Bio sells reagents and instruments used for PCR testing. To give some notable examples, we have been providing large volumes of reagents to reagent manufacturers across the world and used our proprietary technology to develop a SARS-CoV-2 Direct Detection RT-qPCR Kit for detecting the coronavirus that we launched in May 2020. Various issues have been raised with PCR tests for the coronavirus, including that they are complicated to perform and time-consuming, and that the supply chain for test materials is shaky due to strong dependency on foreign products. Our kit addresses these issues.

The main point we focused on when developing this kit was the process of extracting viral RNA from specimens. This process conventionally requires a special extraction and purification kit and takes over an hour, but we made improvements that eliminate the need for a special kit and reduce the time needed to less than 10 minutes. To be more specific, our kit enables preparation of viral RNA for PCR by simply adding a small amount of preprocessed reagent to the specimen containing the virus and heat-treating it. Typically, specimens collected from tested individuals also contain various substances such as proteins, sugars and lipids that inhibit the PCR reaction. Our kit incorporates a unique trick that reduces the effect of these inhibiting substances so they do not interfere with the PCR reaction. In the face of concerns about product shortages for PCR testing, we at Takara Bio are working to ensure a steady supply of products by appropriately scaling our manufacturing and shipping systems to meet society's needs.

We also offer PCR tests for human pathogens such as norovirus, E. Coli O157, and Legionella, as well as for livestock pathogens such as African swine fever and bovine leukosis, which are listed as the Japanese government's official analytical methods* for these applications, and are working to expand the scope of PCR technology in the medical, public health, and environmental fields.

*Methods designated in relevant ministerial notices.

TaKaRa®'s PCR kit, One Step PrimeScript™ III RT-qPCR Mix

Takara Bio's efforts in PCR

PCR technology was invented in the United States in 1983, and an American company later commercialized and sold a PCR system combining reagents and an instrument. Takara Bio (the biomedical business unit of then-Takara Shuzo Co., Ltd.) had launched its bio research reagent business in 1979, and based on the belief that PCR systems would become a platform for all kinds of developments in the life sciences, in 1988 we signed an agreement with the American company with the rights to the system to become the exclusive distributor of that system in Japan. We later received a license to begin manufacturing and marketing reagents in-house as well. At the time in Japan, even bio researchers themselves were not very aware of PCR systems, and the technology did not spread right away. Takara Bio members collaborated with distributors to persistently market the product by visiting research institutions across Japan. As a result, researchers came to understand the benefit of PCR and the technology started to gain traction. By the 1990s, various usages for PCR were being developed, and we saw a substantial jump in sales volume of our PCR-related products.

We support the development and manufacturing of socially impactful gene therapies via CDMO business expansion.

Junichi Mineno
Director and COO

In January of this year, we launched operations at the Center for Gene and Cell Processing II near our headquarters in Kusatsu, Shiga Prefecture. This is a critical facility that will become the hub for our CDMO business. It has over twice the floor space of the original Center for Gene and Cell Processing that began operations in 2014, and with this remarkable increase in manufacturing capability, we will respond to the rapidly expanding CDMO market.

In our CDMO business, we support clients in development and manufacturing of regenerative medicine products such as gene therapies. Specifically, we provide contract services for gene therapy such as manufacturing of vectors* and DNA vaccines, production of transduced cells for injection into humans, and quality testing for these components to clients such as pharmaceutical companies. We also offer other services such as contract genetic testing and genetic analysis as part of our CDMO business. Our CDMO business has been growing rapidly over the past few years, and has become positioned as a critical driver of future growth for the entire company.

Takara Bio's path toward building a CDMO business began in the 1990s, when we developed a platform technology for gene therapy called the RetroNectin® method and quickly launched in-house gene therapy development projects. We established domestic clinical development projects in-house in the mid-2000s, and have begun conducting a clinical trial using transduced cells we produced in-house. At the time, we were probably the only company developing gene therapies in Japan, and there was barely any other activity in the field besides clinical research at a few universities. Even at the global level the situation was the same: gene therapy was a very minor field. There were no companies to provide services necessary for development such as vector manufacturing or cell processing, so Takara Bio members took on that task and headed to laboratories in Europe and the U.S. to exchange information. Later on, the efficacy of gene therapy became widely reported, and the first gene therapy in the world was approved in Europe in 2012.

The trajectory of gene therapy in Japan changed drastically when the Japanese government passed reforms targeting regenerative medicine in 2014. These reforms facilitated development by including gene therapy under a newly defined category of regenerative medicine products and establishing clear regulatory rules. Other countries passed reforms around the same time, and this kicked off serious development of gene therapies at large pharmaceutical companies and drug discovery ventures in Europe and the U.S. all at once.

At Takara Bio, we saw this as a business opportunity. We packaged together the gene therapy technology we had cultivated in-house to date and constructed and opened the Center for Gene and Cell Processing to deliver CDMO services at full scale in 2014. Our services are also designed to ensure compliance with global quality standards for pharmaceutical products and regenerative medicine products (GMP/GCTP). We have created an environment that allows us to satisfactorily meet quality requirements through steps such as acquiring the legally required licenses to do business and obtaining ISO certification for our quality management system.

Due to factors such as the expansion of commercial gene therapy applications from rare genetic diseases to cancer immunotherapy, many more companies are aiming to develop therapies, and the client base for our CDMO business is growing. We will strive to provide high-quality CDMO services for developing gene therapies and other regenerative medicine products by not only appropriately scaling our facilities and equipment but also improving production technology.

*A general term for nucleic acids that carry genes into cells.

Takara Bio's genetic testing and genetic analysis business

In the 1990s, the movement to map the human genome was gaining momentum on a global scale and many universities and other research institutions began routinely performing genetic analysis.

However, due to the large initial investment in equipment and highly specialized knowledge of equipment usage and data analysis required for genetic analysis, there has recently been a shift toward contracting genetic analysis to outside companies. In response to this increased demand for contract services, our Bioindustry business at Takara Bio (the biomedical business unit of then-Takara Shuzo Co., Ltd.) built a large genetic analysis facility equipped with state-of-the-art equipment and powerful computers and began offering contract genetic analysis at full scale. Since then, we have consistently offered our clients state-of-the-art equipment and an extensive portfolio of analytical services to respond to the growing need for genetic analysis. We have also added genetic testing services for individuals to our portfolio in response to the recently growing trend of using individual genetic information from such testing to prevent, diagnose, or treat disease.

Established Takara Group Sustainability Policy

Aims to resolve ESG issues while creating social value through business activities

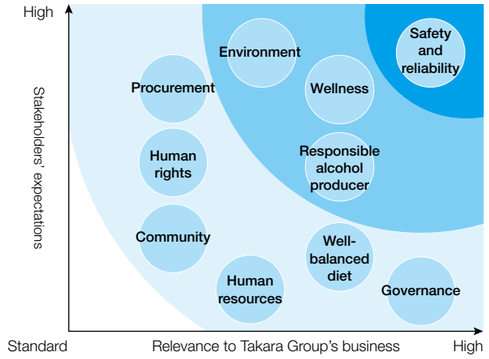
Takara Group Sustainability Policy

In its long-term management vision, “Takara Group Challenge for the 100th” (published in May 2020), Takara Holdings declared that Takara Group would aspire to help people to connect with each other and to realize healthy and fulfilling lives full of smiles. The Group established the Takara Group Sustainability Policy based on the recognition that we will need to take greater initiative to solve various social challenges if we are to continue creating new value in society through our business activities into the future.

As a member of the Takara Group, Takara Bio will also aim to become a company trusted by all its stakeholders and will work to achieve a sustainable society by implementing this Takara Group Sustainability Policy.

Important issues (materiality matrix)

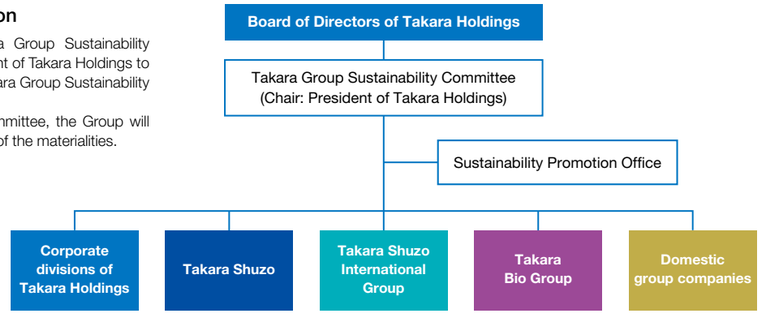
The Takara Group Sustainability Policy takes up ten important issues (materialities), including “safety and reliability,” from the social issues surrounding the Group.



System for implementation

The Group established a Takara Group Sustainability Committee chaired by the President of Takara Holdings to implement the initiatives in the Takara Group Sustainability Policy.

With the leadership of this committee, the Group will implement initiatives around each of the materialities.



E Environment

Fundamental Views on Environmental Activities

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 research and development of merchandise and the procurement of raw materials to production, distribution, sales, and consumption.

Environmental Preservation Strategies

We have adopted structural designs at our headquarters and our primary facilities for manufacturing and research that incorporate innovative technologies with enhanced environmental performance. In particular, we have put in place initiatives to prevent risks from biohazards at our research and manufacturing facilities, and we are aggressively and actively tackling the issues surrounding sustainability, starting with social and environmental problems.

Features of major facilities such as our headquarters and manufacturing and research facilities

- Installed cogeneration systems
- Increased heat insulation in exterior walls and windows
- Used high-efficiency transformers
- Used low-energy LED lighting throughout buildings
- Installed automatic detection systems with motion sensors
- Used water-saving bathroom fixtures
- Enabled environmental monitoring by BEMS*
- Designed buildings (research and manufacturing facilities) to prevent biohazard risk

*Building Energy Management System: A building management system designed to optimize the indoor environment and energy performance.

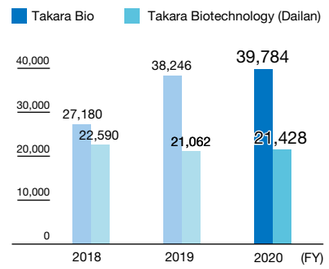
Volume of water used

In fiscal 2019, the volume of water used was 39,784 m^3 at Takara Bio and 21,428 m^3 at Takara Biotechnology (Dalian), our main production hub. These figures were both comparable to last fiscal year.

Prevention of water pollution

Takara Bio 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.

Volume of water used (m^3)



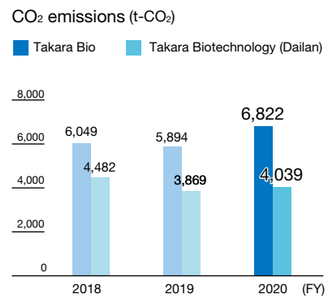
CO_2 emissions

Takara Bio generated 6,822 t-CO_2 of CO_2 emissions in fiscal 2019. This was about 15% higher than the previous fiscal year because of increases in electricity and gas usage due to factors such as starting operations at a new research and manufacturing facility.

Reducing CO_2 emissions with cogeneration systems

Electric-gas cogeneration systems for private power generation are garnering attention as a means for conserving energy and handling energy use restrictions and peak power demand. Takara Bio has installed these systems at our major facilities including our headquarters and research and manufacturing facilities. Going forward, we will strive to reduce our energy usage and CO_2 emissions by effectively using clean natural gas and exhaust heat as fuel for these cogeneration systems.

CO_2 emissions (t-CO_2)



Japan: Calculated from business operator-specific emissions factors based on the Act on Promotion of Global Warming Countermeasures.
Takara Biotechnology (Dalian): Calculated from business operator-specific emissions factors from Northeast China in 2005.

Waste emissions / Amount of chemical substances handled (under PRTR Law)

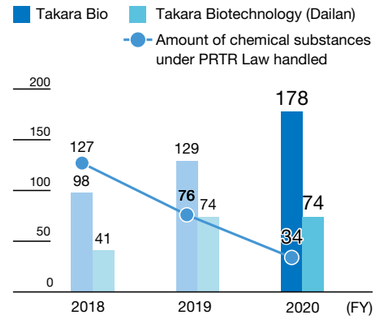
Takara Bio generated 178 t of waste emissions in fiscal 2019, which was a 37% increase from the previous fiscal year. The main reason for this increase was business expansion, including starting operations at a new research and manufacturing facility. The handled amount of specified chemical substances regulated by the Law for Promotion of Chemical Management (PRTR Law)* was only 73 kg, a 55% decrease from the previous fiscal year. The main reason for this decrease was the transfer of our former AgriBio business.

Handling of chemicals based on PRTR

Takara Bio identifies and reports specified chemical substances regulated by the PRTR Law and works to reduce the volume of those chemicals released into the environment.

*Program for registering volumes of release and transfer of substances that could pollute the environment.

Waste emissions (t) / Amount of chemical substances under PRTR Law handled (kg)



S
Social

Fundamental Views on Contribution to Society

We make advancements in the development of gene therapies driven by our proprietary technologies, aimed at patients of rare diseases and serious diseases such as cancer for which treatment methods are yet insufficient. In addition, we make day-to-day efforts to contribute to society by providing researchers worldwide with the research reagents and kits that are essential to leading-edge life sciences research.

Support for Research in the Life Sciences and the Social Implementation of Gene Therapies

We are developing a wide array of products in the life sciences field, ranging from those for basic research to those with industrial applications. In addition to the nearly 10,000 research reagents we produce, we are supporting the growth of research in the life sciences by providing universities and businesses around the world with contract services to support the development and manufacturing of regenerative medicine products. Takara Bio has responded to the increased demand for tests critical to the diagnosis of COVID-19 that began spreading across the globe at the end of 2019 by strengthening our systems for producing PCR reagents and instruments that can be used to detect the coronavirus, and we have quickly supplied large volumes of these products to customers inside and outside Japan. In Japan, we helped to ensure a reliable COVID-19 testing system by getting PCR detection using these reagents and machines covered by national health insurance through the Ministry of Health, Labour and Welfare.

We have also been working to improve access to medical care for rare diseases by using the biotechnology we have cultivated over many years to develop advanced medical technology for clinical development such as gene therapy treatments for rare cancers. We are aiming to bring socially impactful gene therapies to market to address unmet medical needs and help people be well.

Quality Control

Takara Bio and other major subsidiaries across the world have obtained ISO certification, and we continue to strive towards improving the quality of our products and services.

ISO Certification status

Certified organization	Applicable standard
Takara Bio, Inc.	JIS Q 9001:2015 (ISO9001:2015)
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 Limited	ISO9001:2015

The Center for Gene and Cell Processing and its LIC Annex (Kawasaki, Kanagawa Prefecture) are constructing quality control systems based on GCTP/GMP, and have acquired approval to conduct specific processed cell manufacturing. The office also obtained certifications for the manufacturing and marketing of regenerative medicine products in 2019, and newly obtained certification for the manufacturing of biological products and the manufacturing and marketing of in vitro diagnostics in 2020.

In addition, our CDM Center, which offers genetic analysis services and carries out genetic testing support work, has been registered as a CAP/LAP (a certification system for genetic testing laboratories) certified clinical testing laboratory.

Animal Testing with Consideration of Animal Welfare and Handling of Biosafety

We have formulated internal Guidelines on Animal Testing and the Regulations for Implementation of Animal Testing in line with laws, ordinances, and guidelines established by relevant organizations, and make efforts to engage in strict and fair animal testing. Our animal testing facilities have been recognized for their performance of proper animal testing with scientific perspective, under voluntary control efforts and with consideration of animal welfare. The facilities have been accredited by the Japan Health Sciences Foundation's Center for Accreditation of Laboratory Animal Care and Use.

In the area of biosafety, we strive to comply with laws and regulations such as the Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Cartagena Protocol). We have established Genetic Modification Safety Regulations and a Genetic Modification Committee within Takara Bio to strictly review the experiments we conduct in order to preserve biodiversity and ensure safety and health.

Service to Society and Our Local Community

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

Efforts to promote community connections and train the next generation

Every year, Takara Bio executives and employees guest lecture at local universities about the latest trends and future outlook on new modalities in fields such as gene therapy and regenerative medicine from a corporate and business perspective. We also offer university students career planning opportunities by having some new hires visit their alma maters and 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 that incorporates videos. These efforts are popular among community members and they have expressed their hope that we continue them.

Joint research with academic institutions

We are putting effort toward industry-academia collaboration through joint research lectures with universities and other academic institutions.

Examples of major industry-academia collaborations in FY2020

Partner research institute	Theme
The University of Tokyo Hospital	Development of a new approach to cancer immune and gene therapy and methods for evaluating cancer immunity
Mie University Faculty of Medicine	Development of immunotherapy using T cells
Jichi Medical University School of Medicine	R&D for CAR gene therapy and clinical development
University of Toronto (Canada)	Development of new generation CAR gene therapy
Osaka University Graduate School of Medicine	Development and clinical translation of advanced genome medicinal technology

Human Resource Management and Respect for Human Rights

We respect our employees' human rights and are working to achieve a work environment that allows employees to work cheerfully and enthusiastically without fear of discrimination through education and training in accordance with the Takara Group Human Rights Policy.

Cultivation of 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. With our system of stratified training that is carried out according to an employee's position or job-related role, we enable executives, middle management, newly-appointed managers, and mid-level and new employees to acquire the skills needed for their respective positions, to learn about their roles, and to formulate career plans. In addition, we offer a diverse array of objective-based training designed to nurture a can-do attitude in all of the employees in the Takara Group, including our field trip program to the Takara Holdings Corporate History Museum, education and training on compliance, and our study seminar to improve IT skills. We also introduced a compensation system for employee inventions to advance the company's business by encouraging employees to make inventions, as well as protecting and promoting the utilization of those inventions. Our aim with this system is to stimulate intellectual creation efforts and fuel employees' creative drive.

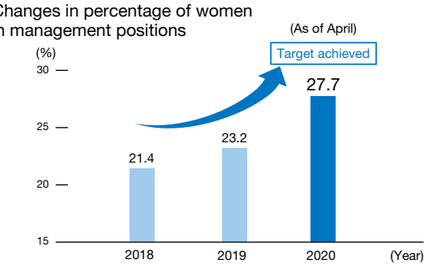
Examples of objective-based training programs in FY2020

Intended participants	Objectives and details
Young tech-oriented employees and those who need the training for their jobs	Intellectual property follow-up training
Employees involved in manufacturing and quality control	Education and training needed for manufacturing control and quality control
All employees	Education and training on compliance
	Study seminar to improve IT skills
	Field trips to the Takara Holdings Corporate History Museum
	Safety confirmation and evacuation drills
	Seminars on trademark law and copyright law

Promotion of diversity and work-life balance

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 women's participation is essential to achieving continued growth going forward, and have taken on promotion of women's participation as an important challenge. We are putting effort toward actively hiring female employees and strengthening women's participation in management. Our class of new hires who started on April 1, 2020 was 60.0% women (9 of 15), making the total percentage of women at the company 41.9%. This includes 27.7% women in management positions (as of April 1, 2020). This percentage is growing steadily every year, so much so that we have already achieved our target set in fiscal 2018 based on the Act on Promotion of Women's Participation and Advancement in the Workplace. In addition, we are making full use of our international human resources and making further progress in diversity across the entire Group.

Changes in percentage of women in management positions



Achieved target based on Act on Promotion of Women's Participation and Advancement in the Workplace (set in FY2018)

We set a target to promote 10 or more women to management positions and to have the total percentage of women in management positions reach 25% or higher by March 31, 2022. (based on number of managers as of the end of March 2016)

In the area of work-life balance, we are aiming 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. To accomplish this, we have introduced systems such as flex time, temporary part-time work for parents, and parental and caregiving leave, and are strengthening systems to promote gender equality aimed at giving equal employment opportunity based on merit.

We are also working to address long working hours and create a comfortable working environment through improving work efficiency by having individual employees re-evaluate their operational setup and how they approach work tasks.

Our Initiatives for Improving Labor Environments

We are working hard to put workplace environments and labor environments in place that will allow our employees to work comfortably. We are also supporting all of our employees in maintaining their health via regular health checkups and mental health care, as well as offering health consultations in coordination with occupational physicians.

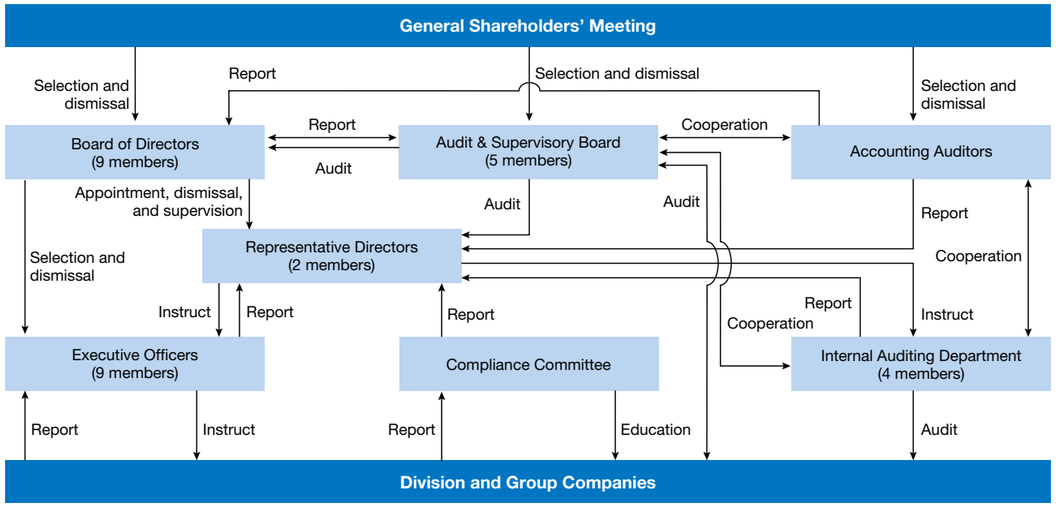
In addition, we have established help lines in Japan and at all our international subsidiaries that enable internal reporting of inappropriate conduct such as harassment, so violations of laws and ordinances and unfair practices are prevented before they can happen.

G
Governance

Fundamental Views on Corporate Governance

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



*Excludes those who are also directors

Our Corporate Governance

Guided by its corporate philosophy to "contribute to the health of humankind through the development of revolutionary biotechnologies such as gene therapy," Takara Bio aims to be a drug discovery company* that continually creates new modalities (treatments) by developing platform technology for biologics discovery through our core businesses of research reagents/scientific instruments and CDMO services. We will continue contributing to society by creating new value and achieving persistent growth through proactive business activities.

Takara Bio believes it is necessary to retain earnings in order to proactively implement R&D in each field. Takara Bio is presently at the stage where it is making prior investments in R&D. The current three-year Medium-Term Management Plan 2023, which will be in its final fiscal year in 2023, promotes our business growth and management base-strengthening strategies. During this three-year period, we will work to realize the goals set forth in our Long-Term Management Plan 2026, which will be in its final fiscal year in 2026, by actively investing in R&D and building a foundation for growth.

It is also our goal to operate in a way that recognizes maintenance of financial health and capital efficiency, as specifically evidenced by the emphasis on operating income (¥10 billion) and ROE (8%) in our current management targets.

In addition, Takara Bio has placed appropriate shareholder return with awareness of capital efficiency as an important issue for management, and is implementing a basic policy of redistributing profits while taking full consideration of business results and financial conditions.

In this way and based on its corporate philosophy, 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 towards establishing the following 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*. The current three-member system of external directors came about via our 17th annual meeting of stockholders in June 2019 in order to pursue sustained growth and medium- to long-term improvement of corporate value. 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

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.

*The Tokyo Stock Exchange has been notified that the three external directors and three external auditors are independent executives.

Evaluating the effectiveness of the Board of Directors

In an effort to improve the functioning of the Board of Directors, we conduct self-completed questionnaires with all directors and auditors, and evaluate the effectiveness of the Board by having the Board review the compiled results. In fiscal 2020, we determined that the Board of Directors was generally functioning as appropriate, and that the effectiveness of the Board overall was being maintained.

Messages from External Directors

Increasing our ability to move the global community

Nobuko Kawashima

I have served as an external director for Takara Bio since June 2016. I teach a discipline called Cultural Economics at Doshisha University, and am the director of its Center for the Study of the Creative Economy. Both of these concepts, of cultural economics and the creative economy, are based on the thinking that creative activities that spark innovation will be the wellspring for economic development in today's age of ubiquitous information and advanced globalization. As a "drug discovery" company that focuses its efforts on R&D, Takara Bio is truly at the forefront of this movement. Takara Bio has the power to not only contribute to the medical field in Japan, but also move the entire global community. Appropriately structured corporate governance is essential for increasing that power even further. Drawing on my experience as an international student and researcher at foreign universities, I will continue contributing to the further advancement of Takara Bio by working to strengthen the company's governance from a broad perspective.

Appointed June 2016/Board of Directors meeting attendance in FY2020: 12 of 12 (100%)

Looking forward to future advancements in biotech

Kazuko Kimura

It is said that "the dose makes the poison," and it was once the standpoint of government agencies and universities to deal with this dual nature of foods, medicines, and chemicals by drawing out their benefits while containing their harmful effects. It is impressive how Takara Bio has carved a path to advanced science and met the needs of the age, even to the point where it has become a creative force that drives those needs. This kind of status can only be attained by many years of hard work combined with accumulated knowledge, technology, and capital, and is not easily reached by rivals. This is also a fortunate job to have because the company's advancement directly contributes to human happiness. We have entered an age where the biotech field and Takara Bio have been able to make breakthroughs even as the field of chemical-based medicine has hit a wall. I am looking forward to a future where we push forward even stronger, being careful not to get arrogant about science but nevertheless feeling full of confidence and pride.

Appointed June 2019/Board of Directors meeting attendance in FY2020: 10 of 10 (100%)

Working diligently to advance Takara Bio as a medical researcher

Noriomi Matsumura

My name is Noriomi Matsumura, and I was just appointed as an external director. Thus far in my career, I have worked in the clinic as an obstetrician/gynecologist while conducting various research projects, particularly research to identify properties of gynecological cancers by genome analysis in order to predict their response to pharmacotherapy. Going forward, I will work diligently to advance Takara Bio by offering my perspective as a physician and medical researcher to the Board of Directors. As the world confronts the spread of COVID-19, Takara Bio is working to make major contributions in the areas of test reagents and vaccine development. It brings me great joy as a medical researcher to be part of this important work at this time. I look forward to continuing to serve Takara Bio.

Appointed June 2020

About Our Parent Company (Takara Holdings)

As of June 26, 2020, Takara Holdings Inc. (first section of the Tokyo Stock Exchange) 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.

The Takara Group has established and put into operation Group Company Management Rules based on its consolidated business management objectives, but those objectives 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.

Compliance

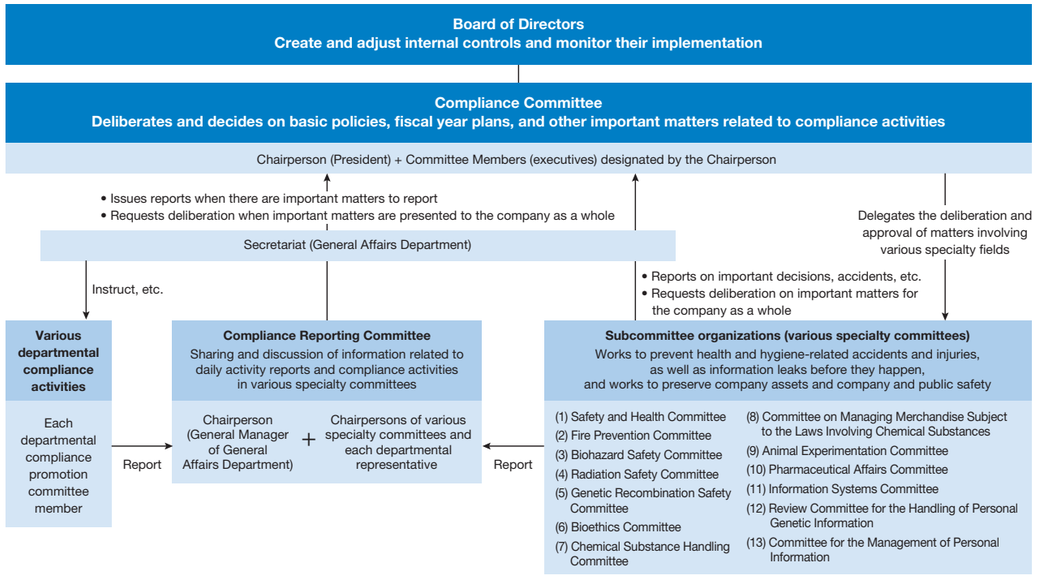
The Takara Group, which includes Takara Bio, has established its own Takara Group Guiding Principles for Compliance Conduct. Each of the Group companies suitably abides by the law and social ethics and undertakes risk management, enabling the Takara Group as a whole to fulfill its corporate social responsibility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

In addition, 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.

Risk Management

Takara Bio 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 introduction 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



ESG Indices

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

		FY2018	FY2019	FY2020
Directors		8	8	9
	Internal directors	6	6	6
	External directors	2	2	3
	Ratio of external directors (%)	25	25	33
Audit & Supervisory Board members		5	5	5
	Internal Audit & Supervisory Board members	2	2	2
	External Audit & Supervisory Board members	3	3	3

Environment-related Information

Items	Applicable companies	FY2018	FY2019	FY2020
CO_2 emissions (t-CO_2)	Takara Bio	6,049	5,894	6,822
	Takara Biotechnology (Dailan)	4,482	3,869	4,039
Waste emissions (t)	Takara Bio	98	129	178
	Takara Biotechnology (Dailan)	41	74	74
Amount of chemical substances handled (under PRTR Law) (kg)	Takara Bio	127	76	34
Volume of water used (m^3)	Takara Bio	27,180	38,246	39,784
	Takara Biotechnology (Dailan)	22,590	21,062	21,428

*See p.18 for calculation methods, etc.

Employee information (Takara Bio Group)

Items	Breakdown		FY2017	FY2018	FY2019
No. of employees by region	Japan		502	480*	517
	Overseas	U.S.	198	207	206
		China	590	588	589
		Europe	76	71	81
		Other	82	89	92

*Temporary decrease due to business transfer during the fiscal year.

Employee Information (Takara Bio)

Items	Breakdown	FY2018	FY2019	FY2020
No. of employees by region	Male	286	287	300
	Female	185	193	217
Diversity	Employees with disabilities (%)	2.2	2.2	2.2
	Women in managerial positions*1 (%)	20.5	20.5	21.4
Status of employees	Average years of service	13 years and one month	13 years and one month	13 years and one month
	Average age	41 years and one month	40 years and 11 months	40 years and 10 months
	Average annual remuneration (Tens of thousands of yen)	615	694	694
	No. of women who have taken childcare leave	8	11	7
	No. of men who have taken childcare leave	0	1	0
	Women who returned to work after taking childcare leave (%)	100	100	100
	Monthly average of overtime hours	16.50	17.75	20.88
	Annual paid holidays taken (%)	8.90	10.63	10.81
	Turnover*2 (%)	11.1	6.7	1.2

*1 Women in managerial position as of the end of March 2016 *2 Turnover of newly-graduated employees who leave within three years of service

Research-related Information—Employees with Major Qualifications

Takara Bio

Breakdown	FY2020
Doctors	67
Pharmacists	20
Veterinarians	3
Clinical technologists	13

Takara Bio USA, Inc.

Breakdown	FY2020
Researchers*	51
Researchers with doctorates	22

*Employees engaged in research

Executives

As of June 23, 2020

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)
President, Takara Shuzo Co., Ltd.
Jun. 2012 Chairman, Takara Holdings Inc. (incumbent)
Chairman, Takara Shuzo Co., Ltd. (incumbent)

Koichi Nakao (CEO)
President, Chairman & President of Subsidiaries, Representative Director

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. 2009 Director, Takara Holdings Inc. (incumbent)
Jun. 2015 Chairman & President of Subsidiaries, Representative Director (incumbent)

Shuichiro Matsuzaki (CFO)
Executive Vice President

Apr. 1980 Joins Takara Shuzo Co., Ltd. (currently Takara Holdings Inc.)
Jun. 2005 Director, Takara Holdings Inc.
Jun. 2007 Director, Takara Shuzo Co., Ltd.
Jun. 2008 Managing Director, Takara Shuzo Co., Ltd.
Jun. 2010 Senior Managing Director, Takara Shuzo Co., Ltd.
Jun. 2014 Senior Managing Director
Jun. 2015 Senior Managing Director & Senior Corporate Executive Officer
Jun. 2017 Executive Vice President & Senior Executive Vice President (incumbent)
Jun. 2019 Executive Vice President (incumbent)

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)

Masanobu Kimura
Director & Senior Executive Officer

May 2013 Joins Takara Bio Co., Ltd.
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
Sep. 1987 Joins Dentsu Communication Institute Inc.
Sep. 1991 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)

Kazuko Kimura
Director (External Director)

Apr. 1976 Joins the Ministry of Health and Welfare (current Ministry of Health, Labour and Welfare)
Jul. 1997 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)

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)

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 (incumbent)
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)

Executive Officers

Yoh Hamaoka
Senior Executive Officer

Kazuki Yamamoto
Senior Executive Officer

Mutsumi Sano
Senior Executive Officer

Katsuhiko Kusakabe
Executive Officer

Akira Kodera
Executive Officer

Noritaka Nishiwaki
Executive Officer

Masanari Kitagawa
Executive Officer

Nobuto Koyama
Executive Officer

Takuya Kakemi
Executive Officer

Contents of the attached document

Net sales

FY2020 was the final year of the 3-year Takara Bio Medium-Term Management Plan 2020, which started in the fiscal year ended March 2018, the Takara Bio Group (the "Group") under the overall policy of the plan continues to promote its efforts to enhance Takara Bio's standing as a global enterprise and manufacturer of regenerative medicine. Net sales for the period decreased by 3.6%, year-over-year, to ¥34,565 million, which was due to the divestiture of the AgriBio Business (both the functional food and the mushroom businesses) in the previous fiscal year as well as other factors, eclipsing a year-over-year increase in the Group's business mainstay in research reagents and contracted services as well as income such as fees from the joint development and exclusive sales agreements for NY-ESO-1·siTCR™ gene therapy drugs and CD19·CAR gene therapy drugs in Japan.

Income

Cost of sales in FY2020 decreased by 11.2% year-over-year, to ¥13,459 million, reflecting the decrease in net sales, a shift in the product composition of the Group and other factors, while gross profit increased by 2.0%, year-over-year, to ¥21,105 million. Selling, general, and administrative (SG&A) expenses decreased by 2.6%, year-over-year, to ¥14,830 million due to lower R&D expenses, etc. As a result of these factors, operating income increased by 14.8%, year-over-year, to ¥6,274 million.

Other income (expenses) decreased by ¥200 million, year-over-year, reflecting factors such as an increase in impairment losses on non-current assets.

This resulted in income before income taxes increasing by 12.7%, year-over-year, to ¥5,433 million. Net income attributable to owners of the parent increased 4.4%, year-over-year, to ¥3,819 million.

Segment Review

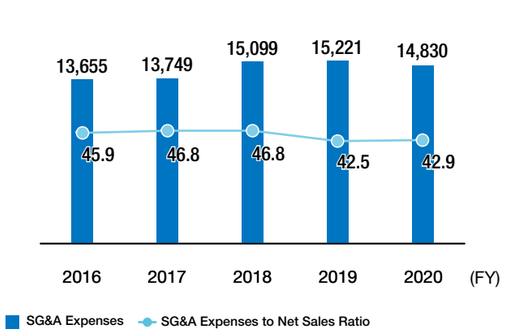
Bioindustry Business

Given the ever-widening activities of biotechnology R&D, the Group has positioned the Bioindustry Business as its core business, which mainly develops products and contracted services supporting such R&D activities.

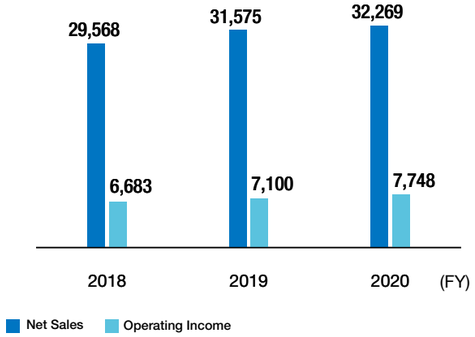
In FY2020, net sales of scientific instruments decreased year-over-year, but net sales of major research reagents and contract research service increased year-over-year.

As a result, the business segment recorded a year-over-year increase of 2.2% in net sales to external customers, to ¥32,269 million. Total income from net sales increased by 6.2% to ¥19,514 million due to an increase in sales. Selling, general and administrative (SG&A) expenses increased by 4.4% to ¥11,766 million due to an increase in R&D expenses, but operating income increased 9.1% year-over-year to ¥7,748 million.

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



Bioindustry
Net Sales / Operating Income (million yen)



Gene Therapy Business

The business focuses on advancing clinical development of gene therapies for cancer and other diseases such as genetically engineered T cell therapies. These therapies utilize the oncolytic virus canerpaturev (C-REV) and original Takara Bio technologies such as the RetroNectin® method for highly efficient gene transduction, the RetroNectin® expansion culture method for the highly efficient expansion culture of lymphocytes, and siTCR™ technology.

For FY2020, the business recorded licensing fees for development and exclusive sales of NY-ESO-1·siTCR™ and CD19·CAR gene therapies in Japan as well as sales of therapeutics and other products related to those contracts.

As a result, net sales to external customers for this business decreased 6.0% year-over-year to ¥2,295 million. Gross profit decreased 17.0% to ¥1,590 million due to factors such as changes in product composition. SG&A expenses decreased 42.5% year-over-year to ¥810 million primarily due to a decrease in R&D expenses, and operating income for the Gene Therapy Business increased 54.1% to ¥780 million.

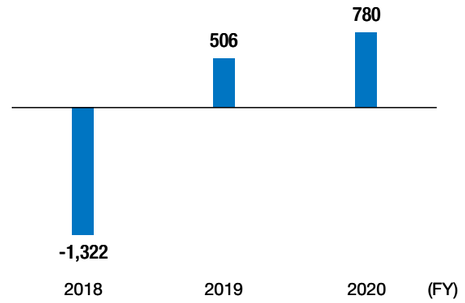
Financial Condition

Total assets at of the end of FY2020 on a consolidated basis were ¥75,009 million, a year-over-year increase of ¥3,969 million. This owed mainly to an increase of ¥2,808 million in property, plant, and equipment reflecting the construction of the Center for Gene and Cell Processing II.

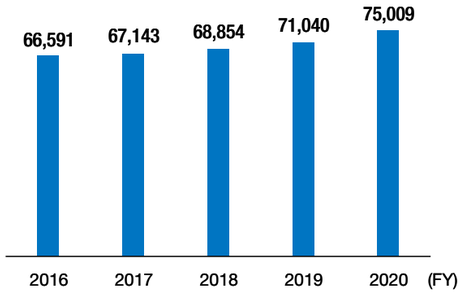
Total liabilities as of the fiscal year-end were ¥8,418 million, a year-over-year increase of ¥1,472 million. This was primarily due to a ¥1,120 million increase in borrowings (current portion of long-term debt and long-term debt) in connection with the new installation of gas engine cogeneration-related equipment.

Total net assets as of the fiscal year-end were ¥66,591 million, a year-over-year increase of ¥2,496 million. This owed mainly to a ¥3,100 million increase in retained earnings and a ¥527 million decrease in foreign currency translation adjustment.

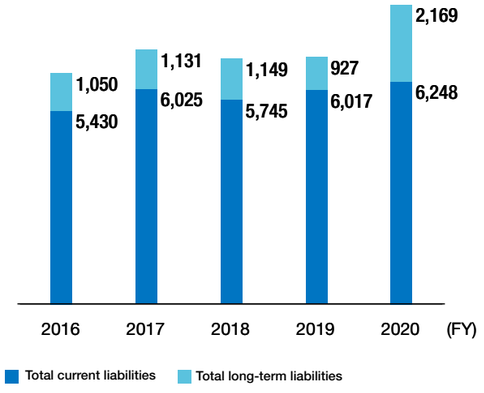
Gene Therapy
Operating Loss (million yen)



Total Assets (million yen)



Total Liabilities (million yen)



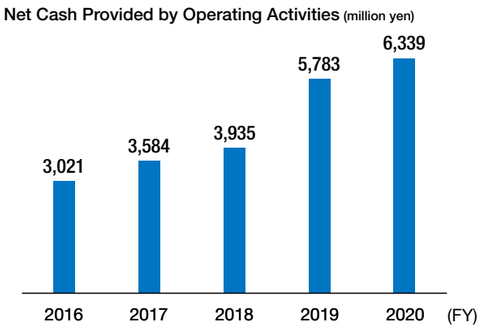
Cash Flows

Net cash provided by operating activities was ¥6,339 million, an increase of ¥556 million compared with the previous fiscal year. Main factors were ¥5,433 million in income before income taxes, ¥3,418 million in depreciation and amortization, an increase of ¥974 million in inventories, and ¥1,247 million in income taxes paid.

Net cash provided by investing activities was ¥212 million, which was ¥5,363 million lower than in the previous fiscal year. Main factors were ¥6,785 million in expenditure from an increase in time deposits, ¥10,515 million in income from a decrease of time deposits, and ¥3,983 million in expenditure for purchases of property, plant, and equipment as well as tangible and intangible non-current assets associated with the construction of the Center for Gene and Cell Processing II.

Net cash used in financing activities was ¥946 million, a ¥404 million increase compared with the previous fiscal year. This was primarily because of a ¥841 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 ¥14,462 million, a year-over-year increase of ¥4,998 million.



Cash Flow from Business Activities

(million yen)	2016	2017	2018	2019	2020
Net cash provided by operating activities	¥3,021	¥3,584	¥3,935	¥5,783	¥6,339
Net cash provided by (used in) investing activities	(4,177)	13,493	(14,755)	(5,576)	(212)
Net cash provided by (used in) financial activities	(221)	(280)	(1,205)	(541)	(946)

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, research departments of 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 medicine, 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, or the occurrence of natural disasters such as earthquakes 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. Nevertheless, the Group is in competition with a number of other companies in the same industry, not only in Japan, but also overseas.

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.

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 are expanding overseas. Thus, a potentially enormous market has opened up, which has prompted many enterprises to conduct R&D for gene therapy, including large pharmaceutical companies and venture businesses in the U.S. and Europe.

Under such circumstances, Takara Bio 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

The Group is based on R&D, and technological innovation is steadily advancing in 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 Takara Bio. In this event, the Group's business strategy and performance could be affected.

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.

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 into yen 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, sales, expenses, assets, and other such line items on the foreign currency financial statements 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. If the expected future cash flow obtainable from an asset decreases because 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 Equity 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.

Contracting company	Takara Bio Inc. (the Company)
Counterparty	Tasly Biopharmaceuticals Co., Ltd. (hereafter, “Tasly”)
Contract name	License Agreement for C-REV
Conclusion date	May 11, 2020
Term	From May 11, 2020, up to 15 years after Tasly’s sales launch of a formulation for commercial use
Summary	Takara Bio grants a license to Tasly for the exclusive development, manufacture, and sales of C-REV in China (including Hong Kong and Macau, but not Taiwan). Takara Bio will transfer C-REV manufacturing technology to Tasly, and Tasly will proceed with clinical development aiming to launch C-REV as a new anticancer drug in China. Takara Bio receives from Tasly an initial payment, contract maintenance payments, and milestone payments according to the progress of development. In addition, after the market launch, Takara Bio will receive running royalties in accordance with sales, and milestone payments when sales targets are achieved.

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 regards securing intellectual rights, including patents, as a critical factor. 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 for any reason or expires, 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., Takara Bio 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 COVID-19 pandemic

The Group expects that the fiscal year ending March 2021 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 strengthening the implementation of remote work modes and other work set-ups that enable social distancing.

5. Parent company of Takara Bio

As of March 31, 2020, Takara Holdings Inc. (listed on the First Section, Tokyo Stock Exchange, hereinafter "Takara Holdings") is the parent company of Takara Bio, owning 60.93% of the voting rights in the Company. 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 proposal to spin off the operations of the company's alcoholic beverage and food business, and the biomedical business with the aim of making the most of the special characteristics of each respective business as well as creating a business environment for increasing growth potential and competitiveness in both. On this basis, Takara Shuzo and Takara Bio were established 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 currently 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, although not currently envisaged, could affect the business and performance of Takara Bio.

3) Transactions with the Takara Holdings Group

(1) Real estate lease transactions related to sales sites

Takara Bio was established as a spin-off company of Takara Shuzo (now Takara Holdings). As a result, the majority of Takara Shuzo's former real estate, including plants, sales offices and company housing, was newly transferred to both Takara Shuzo and Takara Bio. Whereas the alcoholic beverage and food business, and the biomedical business had previously been developed on one site, real estate transactions have occurred with Takara Shuzo and Takara Bio since these transfers. 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, Takara Bio 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, 2020, 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. The above 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

Takara Holdings owns and controls some trademarks used by Takara Bio. Takara Bio has concluded trademark licensing agreements with Takara Holdings with regard to these trademarks and makes a fixed monthly payment per trademark, country, and category based on the number of licenses. As of March 31, 2020, Takara Bio had licenses for the use of 64 registered trademarks and a pending trademark in Japan and overseas.

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

Company name (Location)	Details of transaction	Amount of transaction (Year ended March 31, 2020, 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: The above 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 for any reason, it might affect our business strategies and performance.

Company name (Location)	Details of transaction	Amount of transaction (Year ended March 31, 2020, Millions of yen)	Terms of transaction, etc.
Takara Holdings Inc. (Shimogyo-ku, Kyoto)	Contracting of computer-related services and leasing of equipment, etc.	408	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: The above amounts do not include consumption taxes, etc.

(4) Other

Takara Bio purchases packaging materials, etc., from Takara Holdings Group companies (excluding Takara Bio Group companies). In the event of difficulties in the renewal of these transactions for any reason, it might affect our business strategies and performance.

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	1,485 (consolidated)
URL	www.takara-bio.com

Main Offices

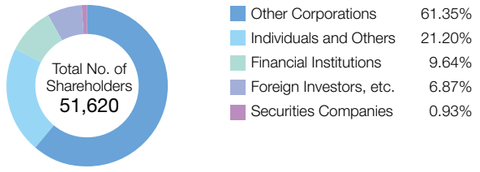
Headquarters	7-4-38 Nojihigashi, Kusatsu, Shiga 525-0058, Japan
Kusatsu Office	7-2-62 Nojihigashi, Kusatsu, Shiga 525-0058, Japan
Tokyo Branch	2-15-10 Nihonbashi, Chuo-ku, Tokyo 103-8232, Japan

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
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	kr2,222 thousand	Production and sales of research reagents, and related contract services

Investor Information

Common Shares	
Authorized	400,000,000 shares
Issued	120,415,600 shares
Total Number of Shareholders	51,620
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)	3,489,900	2.90%
Japan Trustee Services Bank, Ltd. (trust account)	2,725,500	2.26%
THE BANK OF NEW YORK, NON-TREATY JASDEC ACCOUNT	1,350,000	1.12%
Japan Trustee Services Bank, T5	1,065,600	0.88%
JP MORGAN CHASE BANK 385151	701,412	0.58%
STATE STREET BANK WEST CLIENT-TREATY 505234	564,200	0.47%
Japan Trustee Services Bank, T1	548,300	0.46%
Bank of Kyoto	500,000	0.42%
Japan Trustee Services Bank, T2	491,300	0.41%

TAKARA BIO INC.

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