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	(First Section of the TSE, code: 4974)
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Formulation of Medium-Term Management Plan FY2020

Takara Bio Inc. (president: Koichi Nakao) has formulated a new three-year medium-term management plan (hereinafter, "the Plan") that concludes in FY2020 (March 31, 2020).

While the Takara Bio Group has previously reviewed and recreated its management plans on an annual basis, rolling out plans each year as appropriate for the current business environment, this is the Company's first medium-term management plan that looks at a fixed, three-year term. This longer time period allows the Company to aim for more ambitious targets.

Guided by its corporate philosophy of "contributing to the health of mankind through the development of revolutionary biotechnologies such as gene therapy," the Takara Bio Group leverages biotechnology, its fundamental technology, to engage in three businesses: Bioindustry Business, Gene Therapy Business, and AgriBio Business. The Plan aims to strengthen Takara Bio's three business segments and the business base that supports these efforts, to enhance Takara Bio's standing as a global enterprise and regenerative medical products[*1] company, and to achieve prodigious growth overall.

Note 1: A separate category from pharmaceuticals and medical equipment, established under the Pharmaceutical and Medical Device Act. In addition to processed and prepared human cells, tissues, and other products traditionally used for transplants as part of regenerative therapy, it also includes gene therapy products and cell therapies. The system allows regenerative medical products to be quickly approved on a conditional and time-limited basis once their potential effectiveness is identified and their safety verified.

1. Overview of Takara Bio's Medium-Term Management Plan FY2020

Overall Objective	**To strengthen Takara Bio's three business segments, namely, the Bioindustry, Gene Therapy, and AgriBio businesses, and the business base that supports these efforts, enhance Takara Bio's standing as a global enterprise and regenerative medical product[*1] company, and achieve prodigious growth overall.**
Targets	**¥38.5 billion in net sales and ¥4.0 billion in operating income by the final fiscal year of the Plan (FY2020)**
Business Strategies	**= Bioindustry Business =** **Remain number one in CDMO business involving regenerative medical products** **= Gene Therapy Business =** **Aim to acquire approval for the first gene therapy product in Japan** **= AgriBio Business =** **Achieve stable and ongoing profits as our number two profit-making business**

2. Plans for Each Business Segment

(1) Bioindustry Business

FY2020 tangible goals
- Overseas sales ratio of 60% or above
- CDMO business net sales of ¥4.5 billion or above*

***Services only**

The Bioindustry Business aims to achieve prodigious growth by simultaneously expanding business overseas and strengthening domestic business.

Overseas business will leverage the acquisition of WaferGen Bio-systems and Rubicon Genomics to maximize synergy among R&D, manufacturing, and sales. In addition, a global SCM (supply chain management) system will be built in order to provide a worldwide logistics and inventory management system. In R&D, efforts will focus on ramping up research across the four research and development bases that span Japan, the U.S., Europe, and China in the areas of reagents, contracted services, and equipment.

The priority for domestic operations will be expanding CDMO[*2] business, which has seen explosive market growth. With an eye to expanding sales primarily in contracted services, which includes the manufacture of GMP-grade[*3] vectors, quality testing, and others, Takara Bio will reinforce and develop the necessary manufacturing capabilities by developing related technologies and expanding on its facilities and equipment.

Policies for Each Field	
Research reagents	Rapid commercialization of cutting-edge technologies that leverage the open innovation approach
Contracted services	Develop structure based on GMP/GCTP[*3], CAP-LAP[*4], and other quality assurance and accuracy control systems in order to expand contracted services involving regenerative medical products and the clinical field
Scientific instruments	Combine devices and reagents to perform systematized single-cell analysis[*5] methods and develop PCR-related products

Priority R&D Areas for the Bioindustry Business
1. Develop fundamental technologies for regenerative medical products and establish quality control methods
2. Develop an ultra-low-input nucleic acid analysis method
3. Develop new technologies necessary for clinical sequencing
4. Utilize PCR in industrial applications and deploy it in the clinical field
5. Develop new technologies connected to genome editing

Note 2: CDMO is an abbreviation for Contract Development and Manufacturing Organization. It refers to services involving the development of and production support for bio-pharmaceuticals and regenerative medical products.
Note 3: GMP is an abbreviation for Good Manufacturing Practice and refers to the Standards for Manufacturing Control and Quality Control for Pharmaceuticals and Quasi-drugs that must be observed in the manufacture of pharmaceuticals. GCTP is an abbreviation for Good Gene, Cellular, and Tissue-based Products Manufacturing Practices and refers to the Standards for Manufacturing Control and Quality Control for Regenerative Medical Products Manufacturers.
Note 4: CAP (College of American Pathologists) is U.S.-based organization whose primary functions include providing quality management system tools, accrediting laboratories, and providing education. LAP (Laboratory Accreditation Program) is run by CAP and is the world's largest international clinical trial laboratory accreditation program. Inspections of laboratories are carried out once a year, targeting both tangible assets (e.g., clinical testing labs' hardware) and the intangible assets for running such labs (e.g., software).
Note 5: Single-cell analysis refers not to performing standard analysis of cell populations but to genetic analysis at the individual cell level.

(2) Gene Therapy Business

FY2020 business goal
- Domestic Launch of HF10

The Gene Therapy Business will clearly distinguish between independent development projects and joint projects, and by selection and concentration, will aim for quickly obtaining approval for gene therapies.

With its independent development projects, Takara Bio aims to launch the HF10 project in FY2019 and take the first step toward making Takara Bio a manufacturer of regenerative medical products with the goal of launching multiple products in FY2021. Takara Bio will conduct clinical trials according to plan and construct a system for pharmaceutical affairs and manufacturing business aimed at ensuring successful production following product launch.

Independent development projects plan

Independent development projects				Disorders targeted	Present state	Launch target
Oncolytic Virus	HF10		Japan	Malignant melanoma	Phase II clinical trials: In progress	FY2019 (current plan period)
Engineered T-cell Therapy	siTCR	NY-ESO-1	Japan	Synovial sarcoma	Phase I and II clinical trials: Applications submitted	FY2021 (next plan period)
	CAR	CD19 CAR	Japan	Adult ALL[*6]	Phase I and II clinical trials: In progress	FY2021 (next plan period)

Note 6: ALL is an abbreviation for acute lymphoblastic leukemia

Through its joint projects, Takara Bio will work closely with other organizations on domestic HF10 projects. The goal is to complete domestic clinical trials for pancreatic cancer, which is scheduled to begin in FY2018. For other projects, new partners will be selected mostly from outside of Japan.

Joint projects plan

Joint projects plan				Disorders targeted	Present state
Oncolytic Virus	HF10		Japan	Pancreatic cancer	Phase I clinical trials: Preparations underway
			United States	Melanoma	Phase II clinical trials: In progress Phase III clinical trials: Planning underway
Engineered T cell Therapy	siTCR	NY-ESO-1	Japan	Esophageal cancer, etc.	Phase I clinical trials: In progress
		MAGE-A4	Japan	Esophageal cancer, etc.	Phase I clinical trials: In progress
	CAR	CD19 CAR	Japan	Childhood ALL	Planning underway

(3) AgriBio Business

FY2020 tangible goal
- Net sales of ¥2.7 billion and operating income of ¥250 million or above

Takara Bio's AgriBio Business aims to establish the functional foods and mushrooms businesses as pillars to support continuously expanding profits.

In the functional foods business, Takara Bio will focus its research and development (human intervention studies, etc.) on six types of functional ingredients and will proactively publish its results based on the data from that research (through research advertisements and other means). Takara Bio will also closely coordinate with Takara Healthcare Inc. to build a platform for the stable supply of products suited to the Company's sales plan while helping to grow the Takara Group's health food business.

Six functional ingredients currently in development	
Gagome Kombu (Kelp) “Fucoidan”	Agar-derived “Agaphytose®”
Ashitaba (Angelica Herb) “Chalcone”	Herb (Peucedanum japonicum) “Isosamidin”
Yam (Dioscorea esculenta) “Yamsgenin”	Mushroom “Terpene”

Takara Bio's mushroom business will focus on executing brand strategies in the markets for three types of mushrooms (honshimeji, clustered domecap, and brown beech) and will establish a stable revenue base not susceptible to market volatility.

As a part of these strategies, the honshimeji-related business will advertise the strong value of the honshimeji mushroom ("Matsutake for aroma, Shimeji for taste," as the saying goes) and develop a brand of products certified as Kyoto Brand Goods[*7], while also focusing on sales of frozen mushrooms.

Note 7: Certified by the Kyoto Hometown Product Association, Kyoto Brand Goods are particularly high-quality agricultural, forestry, and fishery products and processed foods that are produced in Kyoto Prefecture and that include traditional Kyoto vegetables and other distinctive agricultural products which have been refined over a process of many years.

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