

TAKARA BIO INC.

Corporate Profile

September 8, 2017

Corporate Data

< Corporate Data > ※as of March 31, 2017

- Established : April 1, 2002
- Issued Capital : 14,965 million yen
- President : Koichi Nakao
- Number of employee : 1,344
- Head Office : Kusatsu, Shiga
- Major Shareholder :
Takara Holdings, Inc. (60.91%)

< History >

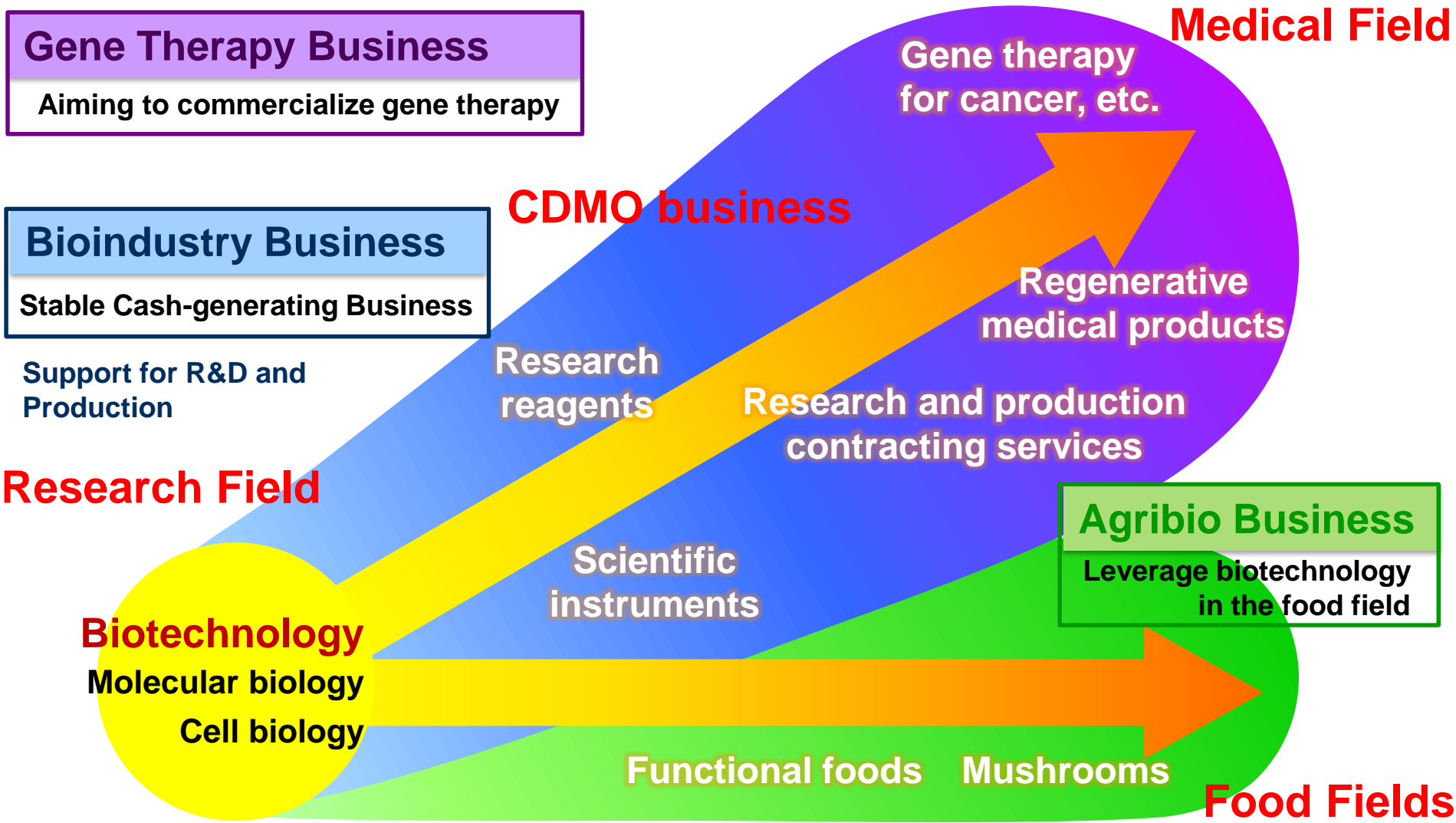
- 1967 Started the biomedical business at TaKaRa Group
- 2002 Established Takara Bio Inc. as a result of corporate separation from Takara Shuzo
- 2004 Listed on the Mothers section of the Tokyo Stock Exchange
- 2014 Started the operation of the Center for Gene and Cell Processing
- 2015 Completed a new facility in Kusatsu, Shiga
Moved the Headquarters office from Otsu to Kusatsu
- 2016 Listed on the First Section of Tokyo Stock Exchange



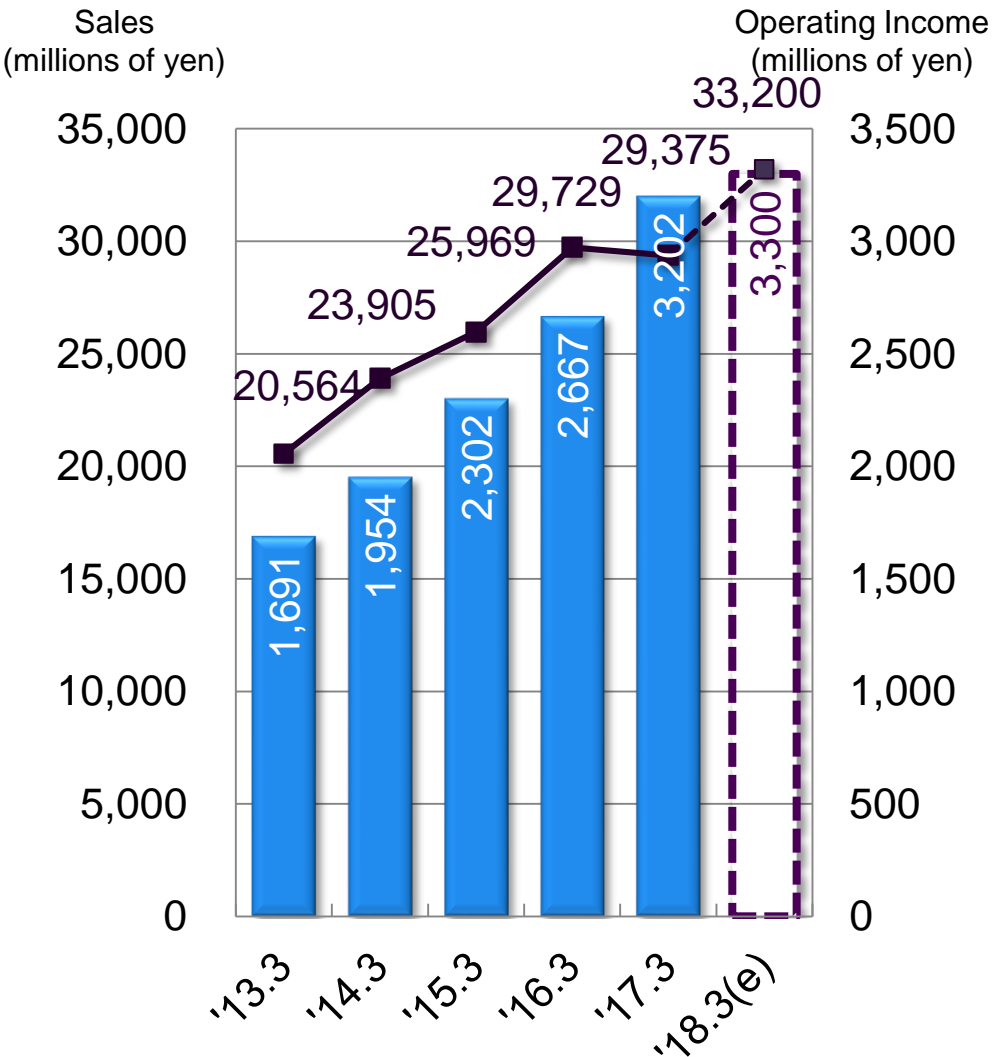
Headquarters Office
and Research Laboratory

Center for Gene
and Cell Processing

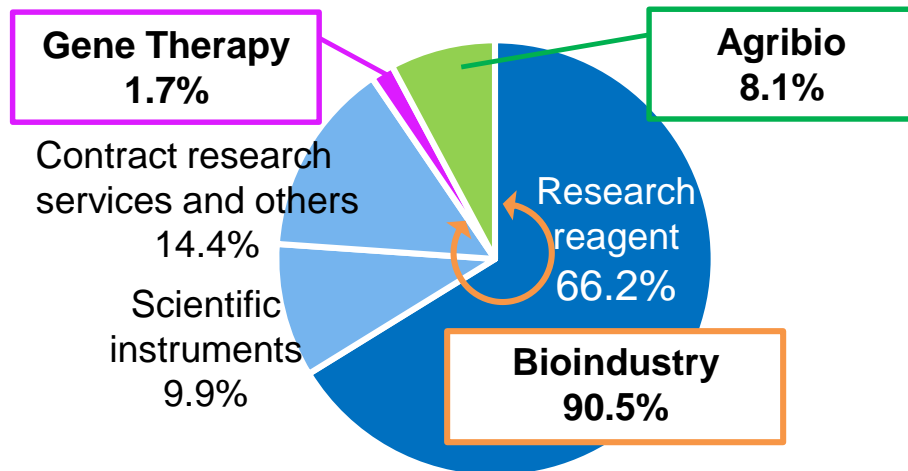
Takara Bio Group's Business Strategy



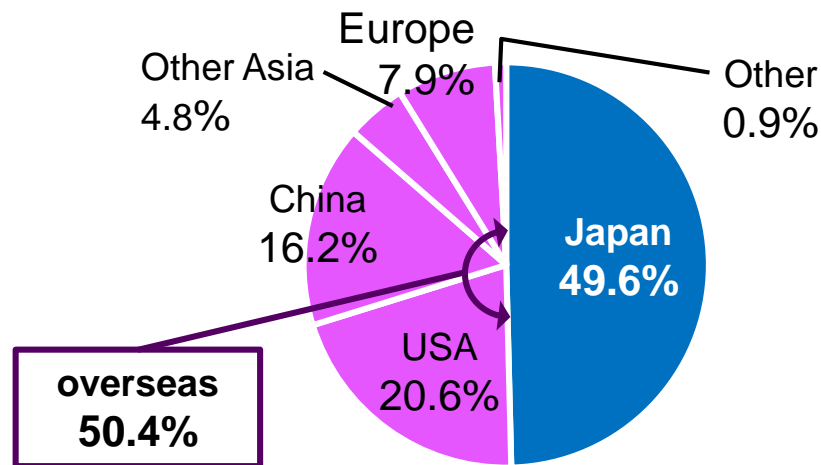
Business Overview



➤ Sales by business category (Fiscal 2017*)



➤ Sales by business area (Fiscal 2017*)



*: Fiscal year ended March 31, 2017

Bioindustry Business

○ Research Reagents

- Gene amplification
- Gene expression
- Next Generation Sequencing etc...



○ Scientific Instruments

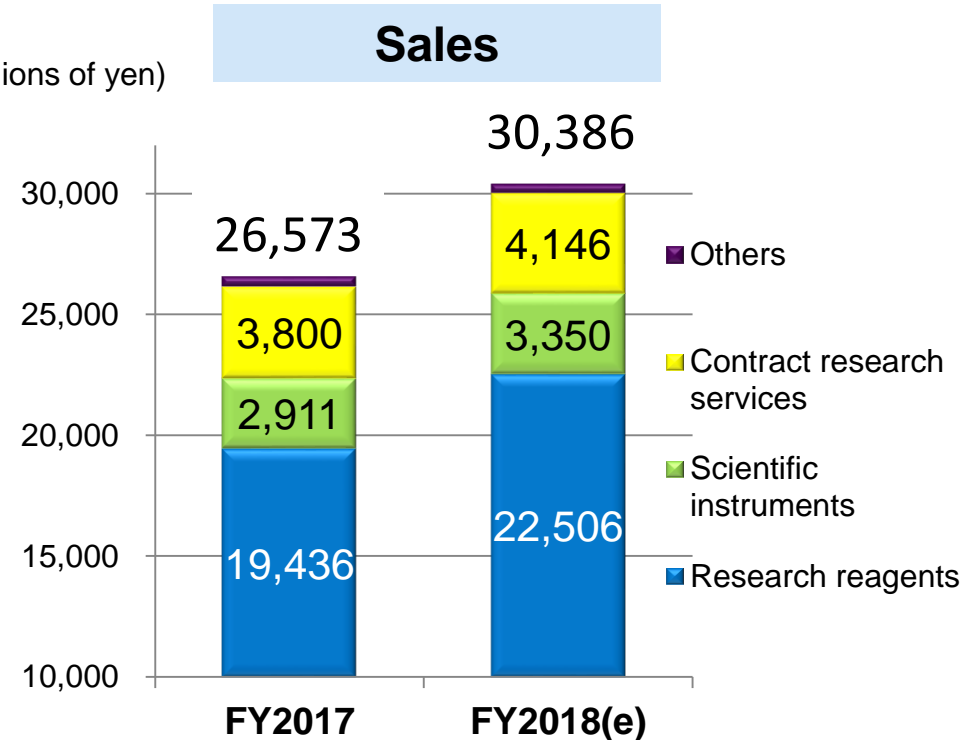
- Gene amplification
- Mass spectrometry systems
- Single-cell analysis systems



○ Contract Research Services

- Genome sequencing analysis
- Vector production, Cell processing
- Technical support and licensing for cancer immunotherapy in clinic etc...

(millions of yen)



Major events in the past

1979

Launching the first Japanese-made 7 restriction enzymes

1988

Commencement of providing PCR system under the exclusive distribution right in Japan

1993

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

2005

Acquisition of Clontech Laboratories, Inc. in the U.S.

2014

Acquisition of Collectis AB in Sweden

2017

Acquisition of WaferGen Bio-systems, Inc. and Rubicon Genomics, Inc. in the U.S.

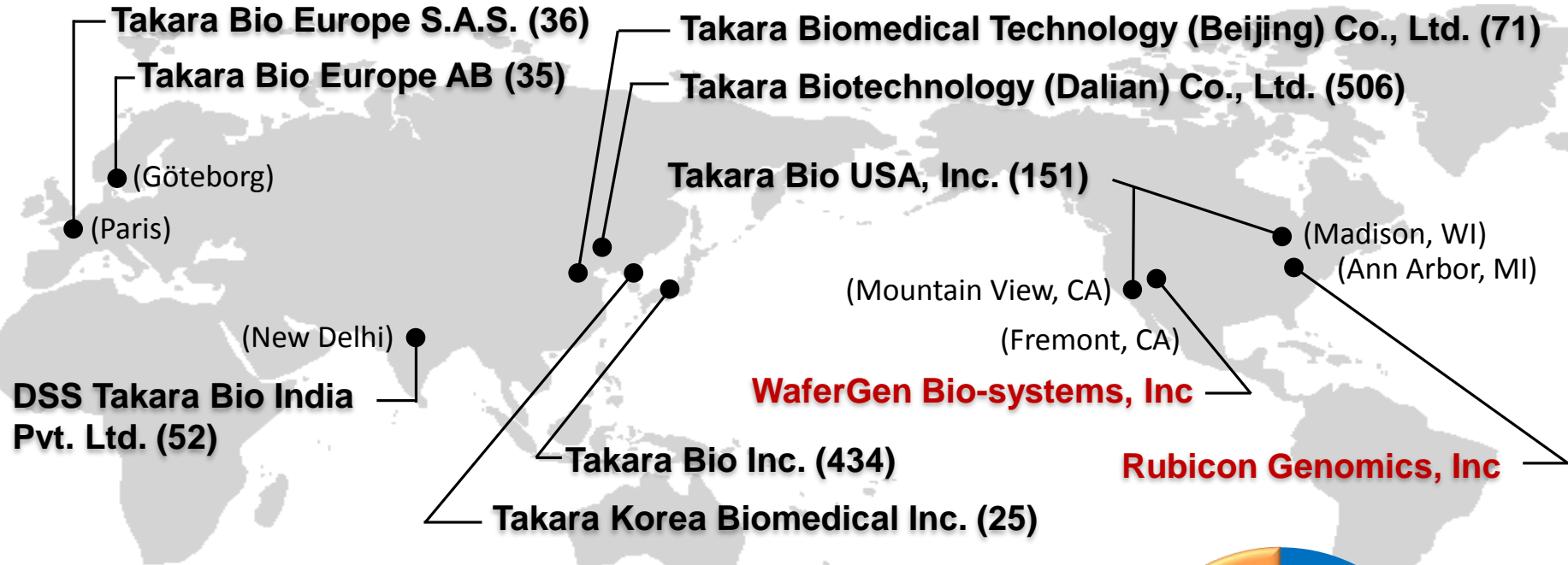
The number of all research reagents available from Takara Bio reaches approximately 7,000



Our major manufacturing facility of research reagents, Takara Biotechnology (Dalian) generates a strongly cost competitiveness

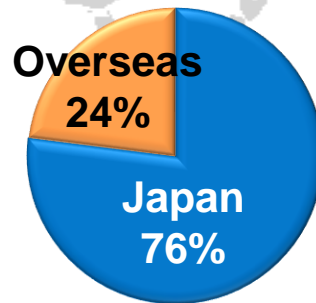


Global Network

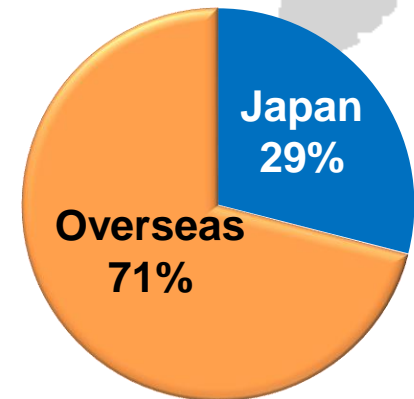


※Number of employees as of March 31, 2017

Geographic turnover of Research reagents



FY2005
6.5 billion yen



FY2017
19.4 billion yen

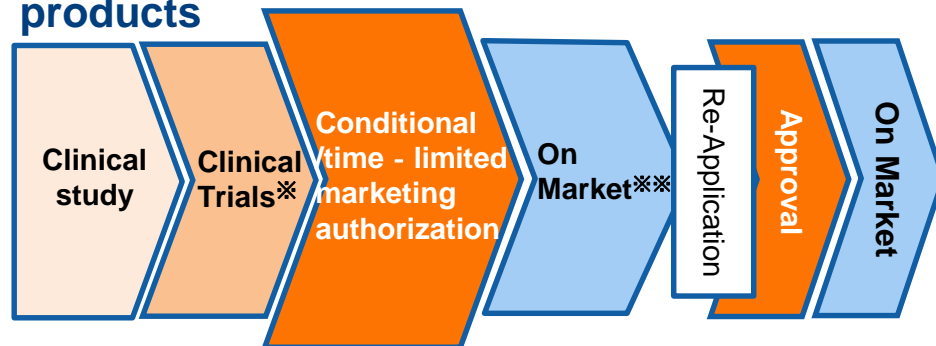
Business Environment for Regenerative Medicine in Japan

Revised Pharmaceutical Affairs Law

Traditional approval Process



New Pathway for regenerative medical products



Leading to Earlier Patient Access !

* predict likely efficacy and confirm safety
 * further confirmation of efficacy and safety

Act on the Safety of Regenerative Medicine

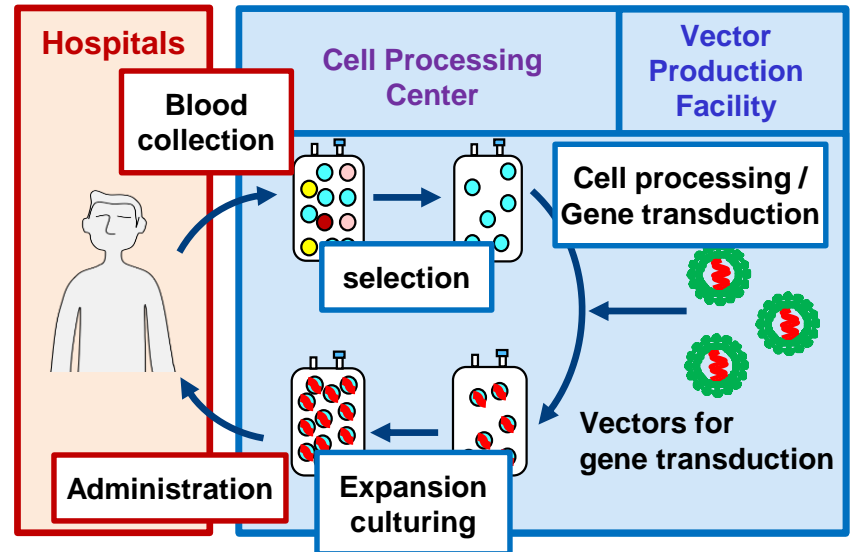
Before

Therapeutic cells can only be processed in hospitals



After November 25, 2014

Cell processing services can be provided by third party companies



Future Prediction for Regenerative Medicine and Cell Therapy Related Market in Japan

◆ Consumables

- Research reagents
- Cell culture media and gas-permeable bags

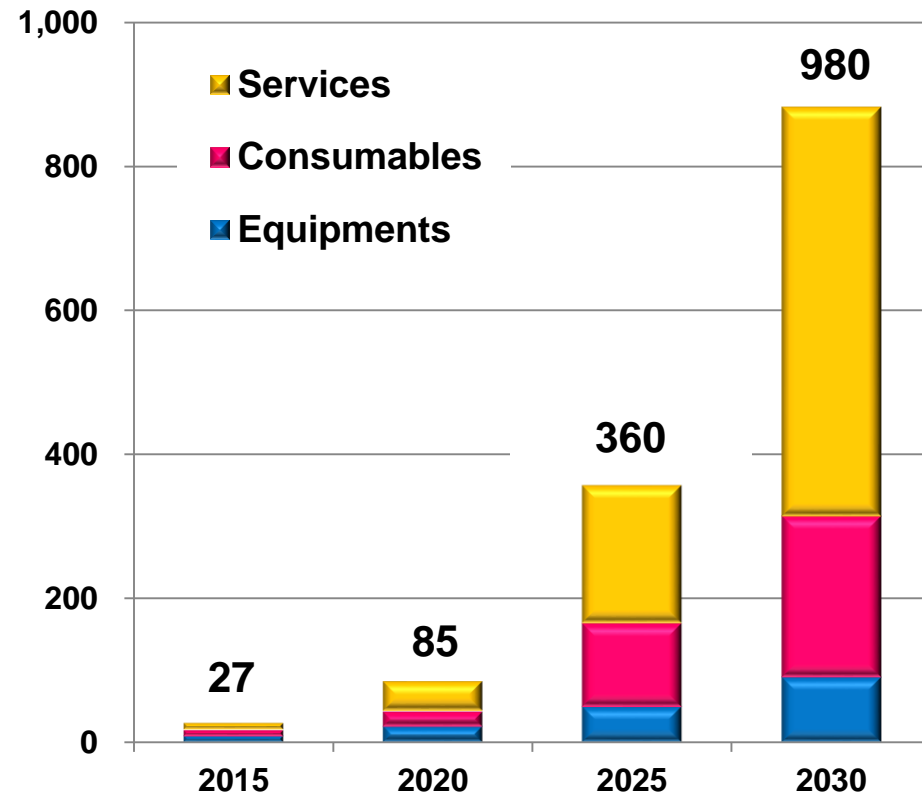


◆ Services

- Cell processing services
- Cell quality management services
- Production of GMP-grade vectors
- Genome sequencing analysis
- Technical support and licensing for cancer immunotherapy in clinic

Size of the national market of regenerative medicine (Related industries)

(Billions of yen)



※ Forum for Innovative Regenerative Medicine [Annual Report 2017]

Center for Gene and Cell Processing



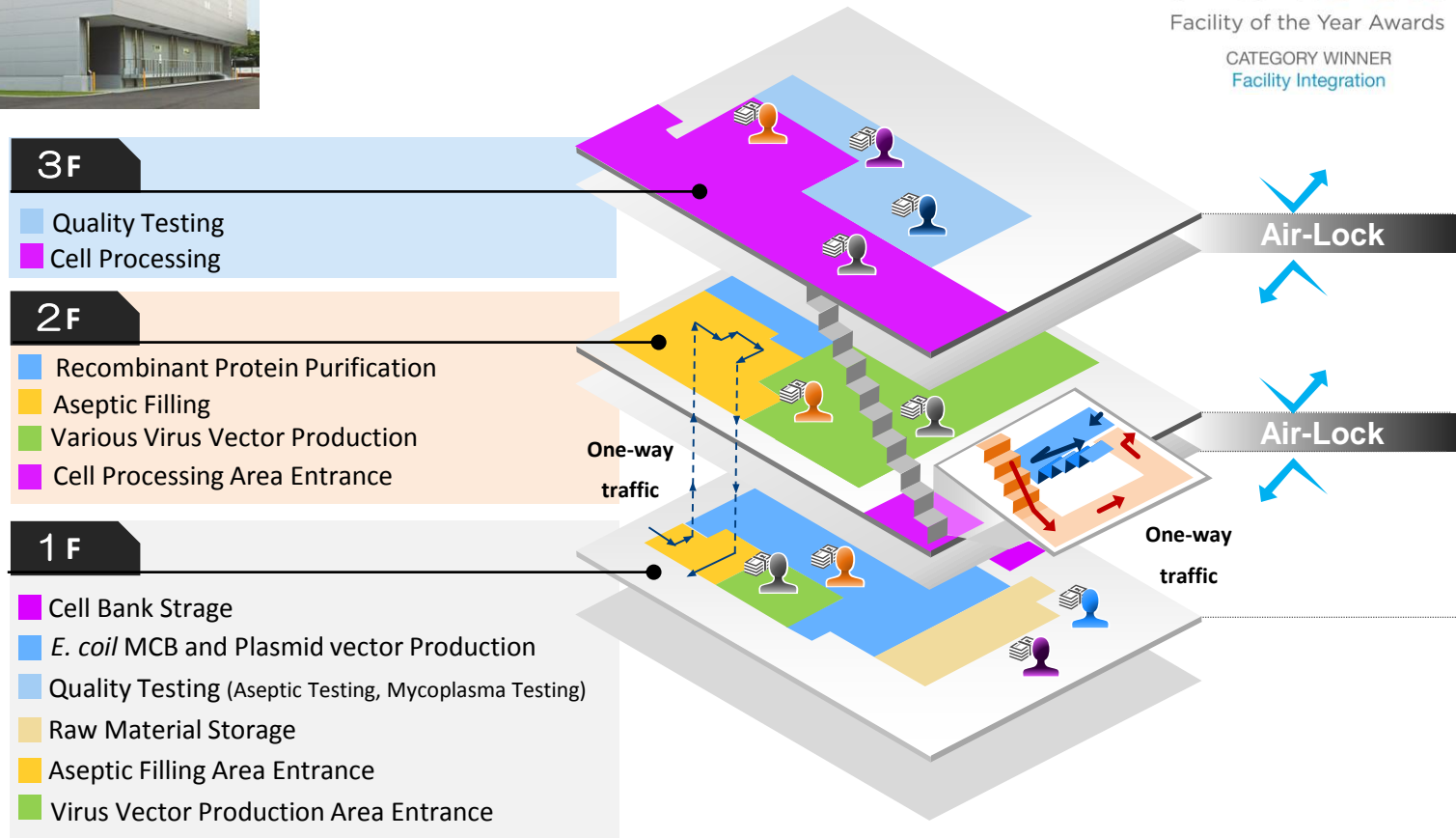
Launch : October 2014
 Location : Kusatsu City in Shiga, Japan
 Full floor space : approx. 6,600 m²



FOYA | 2016

Facility of the Year Awards

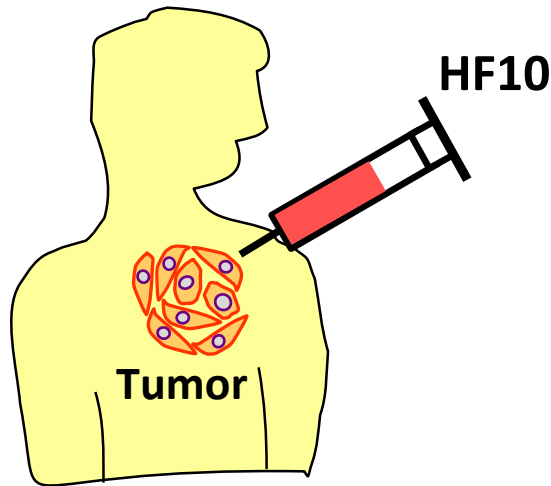
CATEGORY WINNER
 Facility Integration



Clinical Development of the gene therapy for cancers

Oncolytic Virus

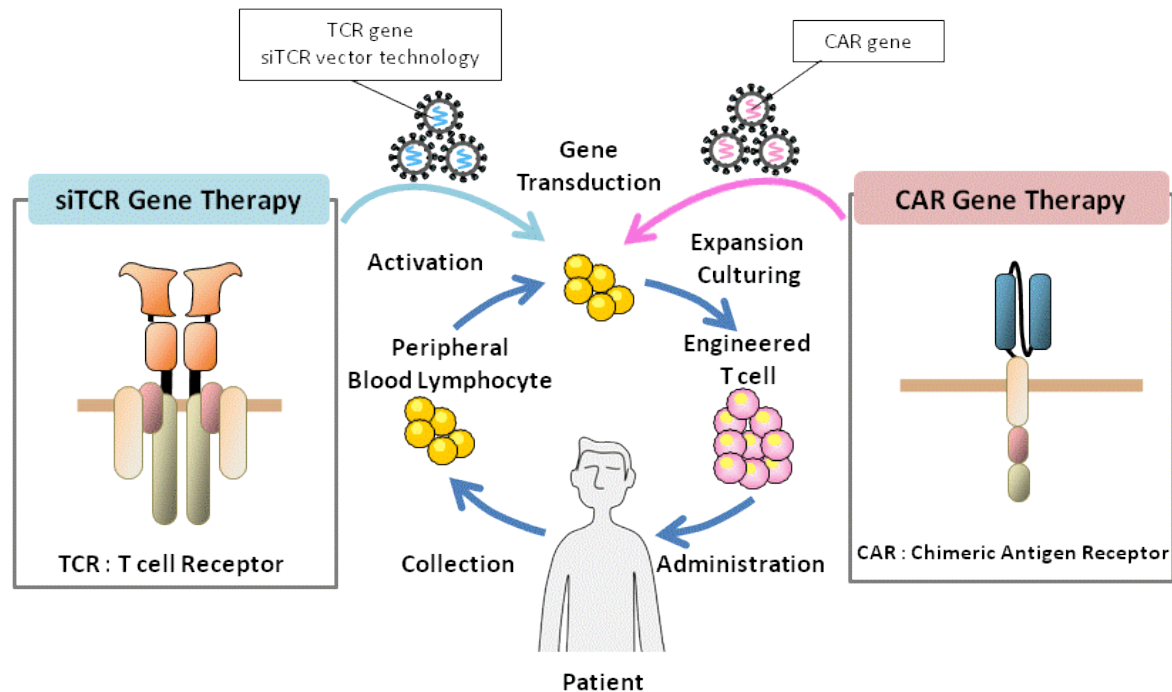
HF10 Anti-cancer Therapy



Engineered T-cell Therapy

siTCR Gene Therapy

CAR Gene Therapy



HF10 Anti-cancer Therapy Project

~ HF10 + Ipilimumab Phase II trial Data ~

Best Overall Response N = 46

	24 weeks	48 weeks
Overall Response (CR + PR)	18 (41%)	20 (45%)
Clinical Benefit (CR + PR + SD)	30 (68%)	30 (68%)
Complete Response (CR)	8 (18%)	8 (18%)
Partial Response (PR)	10 (22%)	12 (27%)
Stable Disease (SD)	12 (27%)	10 (22%)
Progressive Disease (PD)	11 (25%)	11 (25%)
Not Evaluable (NE)	3 (7%)	3 (7%)

**(Reference information)
Best Overall Response**

	Overall Response (CR + PR)
Ipilimumab*	19%
Ipilimumab + Nivolumab*	57%

* Larkin J, et al. N Eng J Med. 2015;373:23-34

Exclusive license agreement with Otsuka Pharmaceutical for co-development and commercialization in Japan of HF10

- ◆ Target disease : pancreatic cancer, melanoma and other tumors
- ◆ Co-develop and Commercialize Area : Japan
- ◆ Upfront and Milestone Payments Total : up to approximately 3 billion yen
- ◆ Takara Bio is to manufacture the HF10 product for use in clinical trials and for post-approval supply in return for unspecified fees to be paid by Otsuka.

post-approval scheme

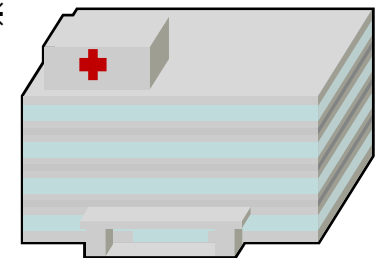


Takara Bio's facility

Manufacture the HF10 product



Marketing HF10[※]



Hospital

※Regenerative medicine

Schedules of Clinical Development of Gene Therapy

Independent development project			Target disease	Progress	Target for commercialization	
Oncolytic Virus	HF10 (TBI-1401)		Japan	Melanoma	Phase II in progress	FY 2019
Engineered T cell Therapy	siTCR	NY-ESO-1 (TBI-1301)	Japan	Synovial sarcoma	Phase I / II in progress	FY 2021
	CAR	CD19 • CAR (TBI-1501)	Japan	Adult ALL*	Phase I / II in progress	FY 2021

Joint project			Target disease	Progress	partner	
Oncolytic Virus	HF10 (TBI-1401)		Japan	Pancreas cancer	Phase I in progress	Otsuka Pharmaceutical
			US	Melanoma	Phase III planning underway	-
Engineered T cell Therapy	siTCR	NY-ESO-1 (TBI-1301)	Japan	Esophageal cancer etc.	Phase I in progress	-
		MAGE-A4 (TBI-1201)	Japan	Esophageal cancer etc.	Phase I in progress	-
	CAR	CD19 • CAR (TBI-1501)	Japan	Childhood ALL*	Planning underway	-

※ALL : B-cell acute lymphocytic leukemia

Agribio Business

○ Functional Foods

Takara Bio develops and manufactures and Takara Healthcare (fellow subsidiary) markets

- Gagome Kombu(Kelp) “fucoidan”
- Herb (*Peucedanum japonicum*) “Isosamidin” etc.



○ Mushrooms

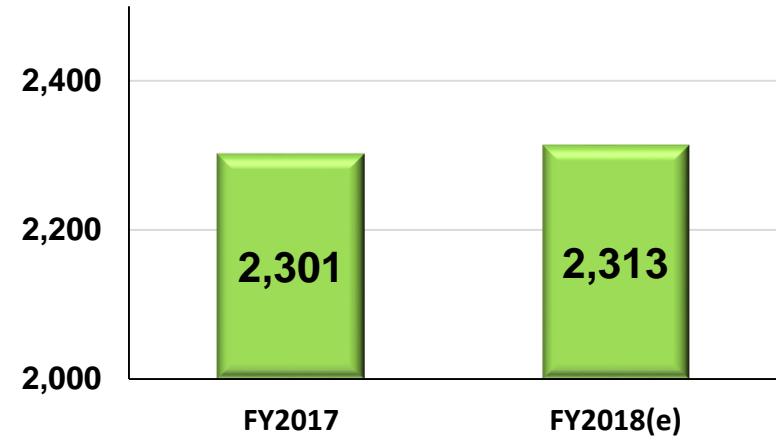
Takara Bio has developed mass production methods of and markets

- Honshimeji mushrooms
- Hatakeshimeji mushrooms
- Bunashimeji mushrooms



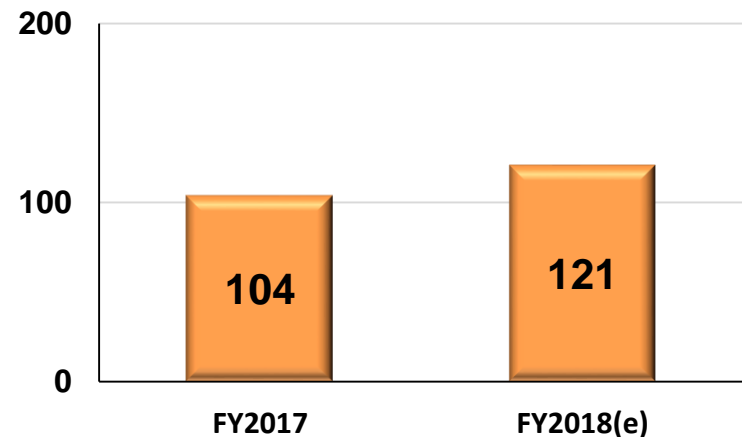
(Millions of yen)

Sales



(Millions of yen)

Operating Income



Forward-Looking Statements

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

<inquiry>

Takara Bio Inc.

Corporate Communications

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