



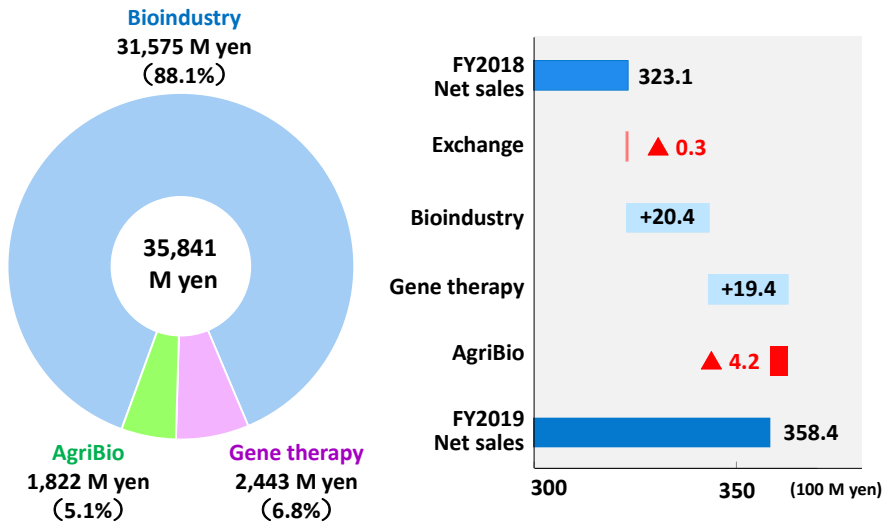
## Annual General Meeting of Shareholders

TAKARA BIO INC.  
June 21, 2019

## Consolidated Financial Results for FY2019

	(M yen)	Y on Y	
		Change	Ratio
Net sales	35,841	+3,528	+10.9%
Cost of sales	15,155	+ 1,497	+ 11.0%
Gross profit	20,685	+2,030	+10.9%
SG&A expenses	15,221	+121	+0.8%
Operating income	5,463	+1,908	+53.7%
Ordinary income	5,665	+1,803	+46.7%
Net income attributable to owners of the parent	3,657	+1,322	+56.6%

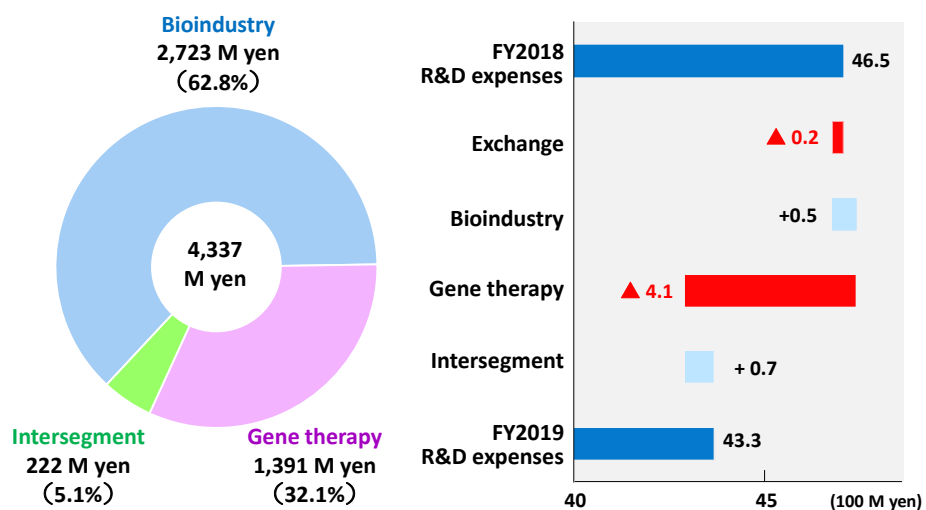
## Business Segment Analysis for Net Sales (Consolidated) for the Year Ended Mar. 31, 2019



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## Business Segment Analysis for R&D expenses (Consolidated) for the Year Ended Mar. 31, 2019

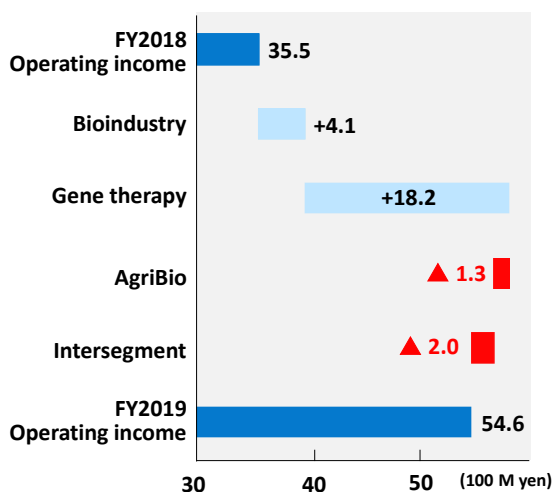


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## Business Segment Analysis for Operating income (Consolidated) for the Year Ended Mar. 31, 2019

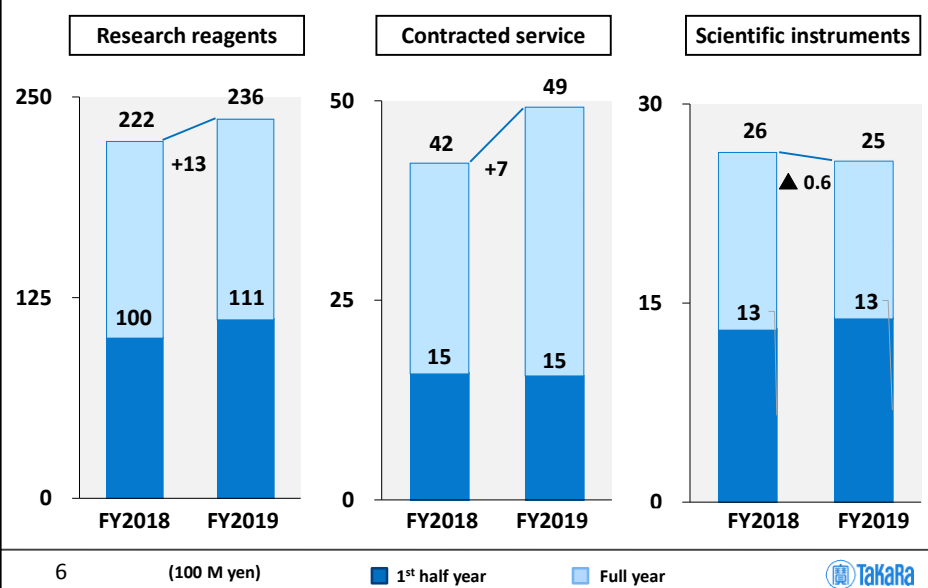
FY2019 Operating income	(M yen)
Bioindustry	7,100
Gene therapy	506
AgriBio	▲ 29
Intersegment	▲ 2,114
Total	5,463



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## Sales by Category in Bioindustry Business for the Year Ended Mar. 31, 2019



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(100 M yen)

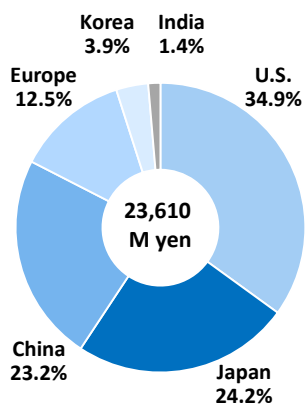
■ 1st half year

□ Full year



## Sales by Region for Research Reagents (Consolidated)

Overseas Sales Ratio : 76%



(M yen)	FY2018	FY2019	Y on Y change	Exchange impact	Y on Y change*
U.S.	7,837	8,230	+393	▲ 128	+521
Japan	5,810	5,715	▲ 95	-	▲ 95
China	4,826	5,470	+643	+29	+613
Europe	2,612	2,948	+335	+81	+254
Korea	841	917	+75	+10	+65
India	278	319	+41	▲ 21	+63

7 \* Exchange excluded



## Overview of Business Transfer of AgriBio

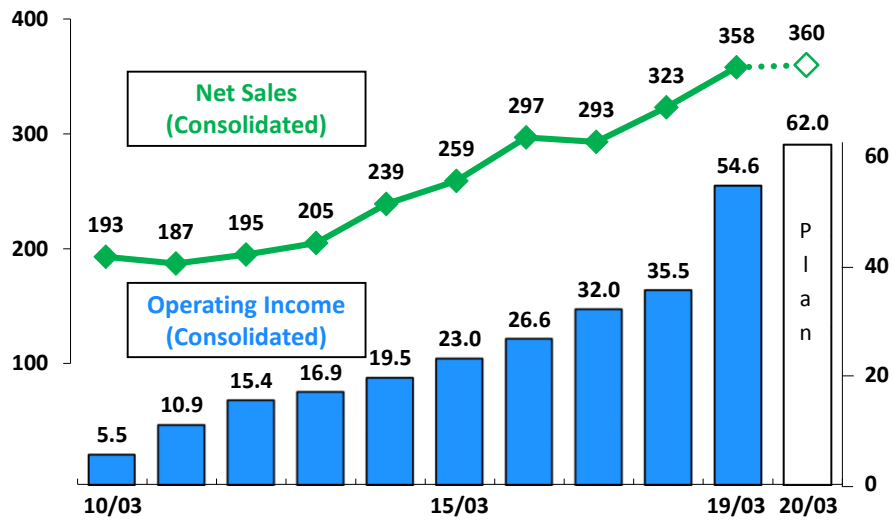
	Functional food business	Mushroom business
Successor company	Shionogi Healthcare Co., Ltd.	Yukiguni Maitake Co., Ltd.
Objective	Business divestiture due to simplified absorption-type company split (Primary asset succeeded) •All shares of Takara Bio Farming Center Inc. owned by Takara Bio •IP relating to functional food business	•All shares of Mizuho Norin Co., Ltd. and KINOKO CENTER KIN INC. owned by Takara Bio •IP relating to mushroom business
Closing	January 1, 2019	March 1, 2019

(M yen)	FY2019	Y on Y change	
Net sales	1,822	▲ 421	▲ 19.8%
Operating income	▲ 29	▲ 136	-

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## Consolidated Net Sales and Operating Income in Last 10 Years



9 (100 M yen)



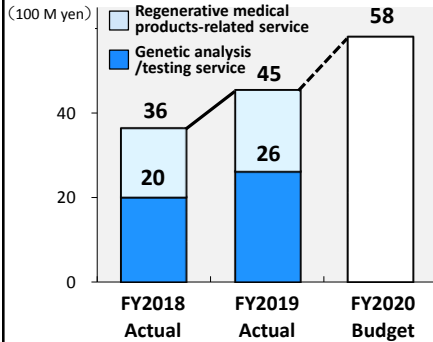
## Consolidated Financial Results for FY2019 (Non-Consolidated)

	(M yen)	Y on Y	
		Change	Ratio
Net Sales	21,740	+764	+3.6%
Cost of sales	12,097	▲ 322	▲ 2.6%
Gross profit	9,643	+1,087	+12.7%
SG&A expenses	7,330	▲ 324	▲ 4.2%
Operating income	2,312	+1,411	+156.7%
Ordinary income	3,690	+1,030	+38.7%
Net income	2,756	+1,351	+96.2%

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## Bioindustry Business ① CDMO Business Expansion



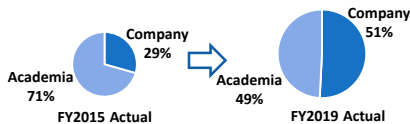
### Regenerative medical products-related service Respond to increasing service orders

- ① In construction for research and manufacturing facility of regenerative medical products
- ② Develop GMP vector manufacturing on a large scale and cell processing technique
- ③ Develop quality testing for regenerative medical products

### Genetic analysis/Genetic testing service Aim for high-value added supply such as accuracy assurance which overcomes competitors

- ① Expand service menu for gene analysis such as whole genome sequencing
- ② Strengthen the fields of single cell analysis and clinical sequencing

### Client profile in CDMO business

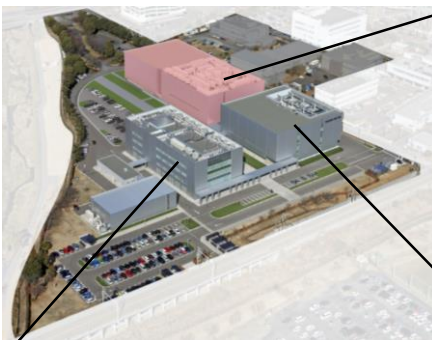


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## Bioindustry Business ②

### In Construction for Research and Manufacturing Facility



### New construction (About 14,500 m<sup>2</sup>)

- Plan for further expanding QC area and increasing capacity for vector manufacturing
- Make system responding flexibly to CDMO service with 4,600 m<sup>2</sup> backup space

### Main research facility (Lab area about 1,200 m<sup>2</sup> on 3<sup>rd</sup> FL)

- Expand NGS area

### Center for Gene and Cell Processing (About 6,700 m<sup>2</sup>)

- Use continuously QC area
- Strengthen cell processing capability with additional operation in CPR at LIC, Kanagawa pref.

12 CPR : Cell Processing Room



## Bioindustry Business ③

### Sales Plan by Region for Research Reagents

	FY2019 Actual	FY2020 Budget	Y on Y change	Y on Y ratio
U.S. (Thousand dollar)	74,515	81,633	+7,118	+10%
Japan (Million yen)	5,715	6,190	+475	+8%
China (Million yuan)	327	354	+27	+8%
Europe (Thousand euro)	22,618	25,218	+2,600	+11%
Korea (Million won)	9,138	9,877	+738	+8%
India (Million rupee)	197	236	+39	+20%
Exchange-reflected total (Million yen)	23,601	24,990	+1,389	+5%

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## Gene Therapy Business ① Pipeline Status for developing

Project		Indications	Status	Partnership		
Oncolytic virus	C-REV (TBI-1401)  Nonproprietary name : canerpaturev Trade name : EPLICANA*	Japan	Malignant melanoma	Applied for marketing approval	Otsuka Pharma	
		Japan	Pancreatic cancer	Phase I in progress	Otsuka Pharma	
		Korea	All indications	Under review	Dong-A ST Co., Ltd.	
		U.S.	Malignant melanoma	Phase II Investigator initiated trial in progress	Under review	
Engineered T cell therapy	CAR	CD19 (TBI-1501)	Japan	Adult ALL* <sup>1</sup>	Phase I/II in progress	Otsuka Pharma
				Expand indications	Under review	Otsuka Pharma
	siTCR*	NY-ESO-1 (TBI-1301)	Japan	Synovial sarcoma	Phase I/II in progress	Otsuka Pharma
				Expand indications	Under review	Otsuka Pharma
	Canada	Solid cancer	Phase Ib Investigator initiated trial in progress	Under review		

14 \* ALL : Acute lymphoblastic leukemia



## Gene Therapy Business ②

### Developmental Status of Oncolytic Virus C-REV Project

#### Joint/Licensing agreement

- ◆ Otsuka Pharmaceutical, Co., Ltd.  
(December 15, 2016)
  - Region : Japan, All indications
  - Otsuka : Clinical trial and exclusive sales, etc.
  - Takara : Manufacturing, etc.
- ◆ Dong-A ST Co., Ltd., South Korea  
(August 22, 2018)
  - Region : Exclusive in Korea, All indications
  - Dong-A ST : Clinical trial, Marketing approval acquisition, and exclusive sales, etc.
  - Takara : Manufacturing, etc.

#### Manufacturing/Sales system

- ◆ Manufacturing certificate received  
(March 2019)
- ◆ Marketing certificate received (May 2019)

#### Clinical development/ Conference presentation

- ◆ Malignant melanoma (Japan)
  - Applied for marketing approval (March 2019)
  - Presented at ASCO 2019 (June 2019)
- ◆ Malignant melanoma (U.S.)
  - Investigator initiated clinical trial Enrollment in Phase II completed
- ◆ Pancreatic cancer (Japan)
  - Phase I clinical trial (expansion cohort) in progress
  - Presentation of preliminary data for dose titration at ASCO-GI 2019 (January 2019)

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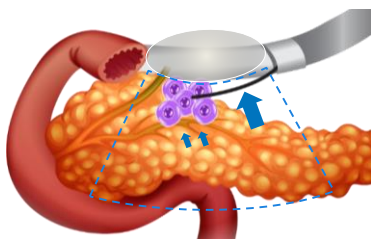


## Gene Therapy Business ③

### Phase I Trial of C-REV for Pancreatic Cancer (Dose Titration Stage)

#### Intratumoral injection by EUS-guidance

- In use extensively of fine needle aspiration (FNA) with endoscopic ultrasound (EUS) applicable to testing and diagnosis for pancreatic cancer
- C-REV injection with same equipment and technique



#### Best overall response rate (N = 6)

	16 wks	After 16 wks
<b>Objective response (CR + PR)</b>	1 (17%)	4 (67%)
<b>Disease stability rate (CR + PR + SD)</b>	6 (100%)	6 (100%)
<b>Complete response (CR)</b>	0 (0%)	0 (0%)
<b>Partial response (PR)</b>	1 (17%)	4 (67%)
<b>Stable disease (SD)</b>	5 (83%)	2 (33%)

16 Presented at ASCO-GI : American Society of Clinical Oncology Gastrointestinal Cancers Symposium 2019 Congress (January 2019)





## Gene Therapy Business ④

### Developmental Status of CD19 • CAR Project

#### Joint/Licensing agreements

- Otsuka Pharmaceutical, Co., Ltd. (April 9, 2018)
- Region : Japan, All indications (First refusal right for 9 Asian countries)
- Otsuka : Clinical trial, exclusive sales, etc.
- Takara : Manufacturing, etc.
- Preparation underway for expand indication

#### Trial for adult ALL (Japan)\*1

- Phase I/II in progress
- Target number cases : 21 cases
- Follow up of procedure when CRS is expressed\*2
- Preparation underway for Orphan drug application

#### Increase institutes toward accelerating trial

- Trial institutes increased from 6 places to 11 places
- Screening difficulty to satisfy trial criteria because disease for adult ALL is rapidly progressed
- Marketing change accompanying competitive products approved during trials
  - ① Inotuzumab ozogamicin (Approved in January 2018)
  - ② Blinatumomab (Approved in September 2018)
- Indication objective is different : Indication of “Kimriah” approved in Japan is childhood/juvenile ALL and DLBCL\*3, while indication evaluable in this trial is adult ALL

17 \* 1 ALL : Acute lymphoblastic leukemia \* 2 CRS : Cytokine release syndrome  
\* 3 DLBCL : Diffuse Large B-cell Lymphoma



## Gene Therapy Business ⑤

### Developmental Status of NY-ESO-1 • siTCR™ Project

#### Joint/Licensing agreements

- Otsuka Pharmaceutical, Co., Ltd. (April 9, 2018)
- Region : Japan, All indications (First refusal right for 9 Asian countries)
- Otsuka : Clinical trial and exclusive sales, etc.
- Takara Bio : Manufacturing, etc.
- Preparation underway for expand indication

#### Trial for synovial sarcoma (Japan)

- Phase I/II in progress
- Target number cases : 8 cases
- Product designation under “SAKIGAKE Designation System” succeeded to Otsuka

#### Phase Ib Investigator initiated trial (Canada)

- Preliminary data presented at ASCO 2019 (June)
- Study patient : Solid cancer
  - ① HLA-A\*02:01 or HLA-A\*02:06 positive
  - ② NY-ESO-1 antigen positive
- Administration plan/Dose
  - ① Prior treatment : Cyclophosphamide 750 mg/m<sup>2</sup> x 2 days
  - ② TBI-1301 5x10<sup>9</sup> cells
- Evaluable patients : 8 cases
  - ① Tumor shrinkage : PR 2 cases, SD 5 cases, PD 1 case
  - ② Safety : No DLTs reported  
CRS expressed in 5 cases (Grade 1 – 2)
  - ③ Observed persistence inside body for more than 100 days after administration

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## Focus on Creating New Clinical Projects and Developing Platform Technology

- Develop new CAR structure (intracellular domain for signal transduction such as G1TR and JAK/STAT)
- Screening of new cancer antigen for T cell : Leverage Neoantigen analysis
- Develop new virus vector for gene therapy and establish production technique on a large-scale\*
- Develop basic technology, aimed at improving productivity for gene-transduced cells (leading to cost down)
- Develop liquid biopsy applicable to cancer immune therapy and basic technology related to clinical sequencing

19 \* Started AMED project "Research and development of core technologies for gene and therapy" from April 2019



## Progress of "Medium-Term Management Plan FY2020" (Formulated in May 2017) ①

Business goal	Status as of March 2019
<p style="text-align: center;"><b>Bioindustry</b></p> <p>Regenerative medical products-related CDMO business No.1</p>	<ul style="list-style-type: none"> <li>• Expanding CDMO business for vector manufacturing, cell processing, quality testing</li> <li>• In construction currently for research and manufacturing facility (Scheduled for completion in December 2019)</li> </ul>
<p style="text-align: center;"><b>Gene therapy</b></p> <p>Approval acquisition of gene therapy products</p>	<ul style="list-style-type: none"> <li>• Applied for marketing approval of C-REV in Japan (Malignant melanoma)</li> <li>• Cooperated on projects: oncolytic virus and genetically-engineered T cell therapy</li> </ul>
<p style="text-align: center;"><b>AgriBio</b></p> <p>Building a platform for stable profits</p>	<ul style="list-style-type: none"> <li>• "Selection and concentration" in business operation : Business transfer of functional foods and mushrooms</li> </ul>

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## Progress of “Medium-Term Management Plan FY2020” (Formulated in May 2017) ②

### FY2020 Takara Bio consolidated results

**Net sales 38.5 billion yen**  
**Operating income 4.0 billion yen**



Income target revised upwardly but sales target revised downwardly due to AgriBio business transfer, etc.

### FY2020 Takara Bio consolidated results

**Net sales 36.0 billion yen**  
**Operating income 6.2 billion yen**

### Consolidated operating income

