

## **Contents**

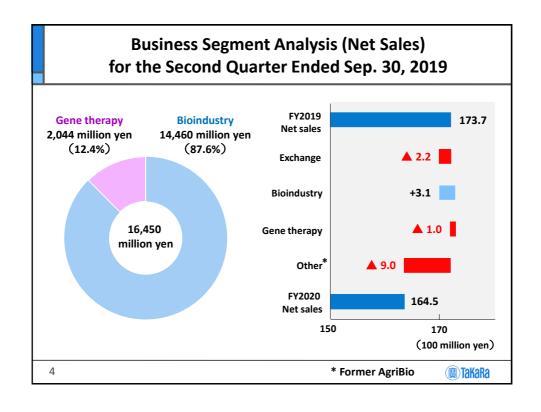
- Consolidated Quarterly Financial Results for FY2020\*
   (For the Second Quarter Ended Sep.30, 2018)
- FY2020 Forecast
- Status Overview of Primary Project

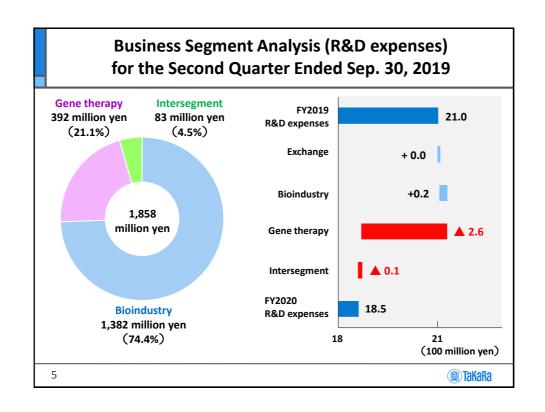
\* FY2020 refers to the fiscal year ended March 2020

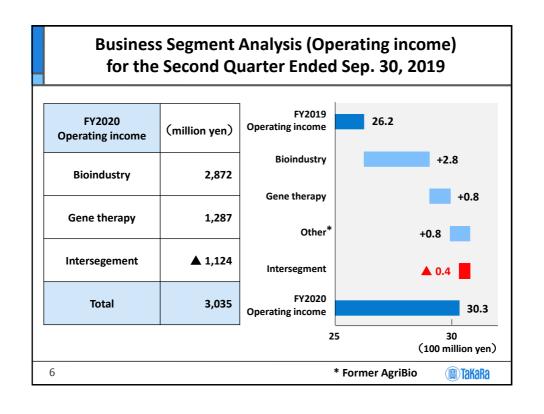
# **Consolidated Quarterly Financial Results for FY2020** (For the Second Quarter Ended Sep. 30, 2019)

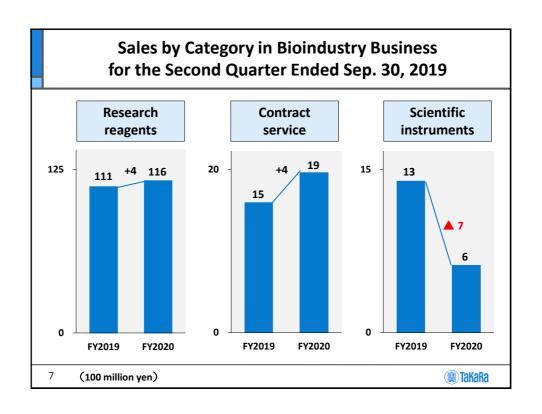
	FY2020	Compared with previous forecast		Y on Y	
(million yen)	(2ndQ)	Change	Ratio	Change	Ratio
Net sales	16,450	<b>▲</b> 678	<b>4.0%</b>	<b>▲</b> 919	▲ 5.3%
Cost of sales	6,121	<b>494</b>	<b>▲</b> 7.5%	<b>▲</b> 927	▲13.2%
Gross profit	10,329	<b>184</b>	<b>1.8%</b>	+7	+0.1%
SG&A expenses	7,293	▲ 302	<b>4.0%</b>	<b>4</b> 04	▲ 5.2%
Operating income	3,035	+117	+4.0%	+411	+15.7%
Ordinary income	2,961	▲ 39	<b>1.3</b> %	+292	+10.9%
Net income attributable to owners of the parent	2,075	+125	+6.4%	+354	+20.6%
3					<b>園TaKaRa</b>

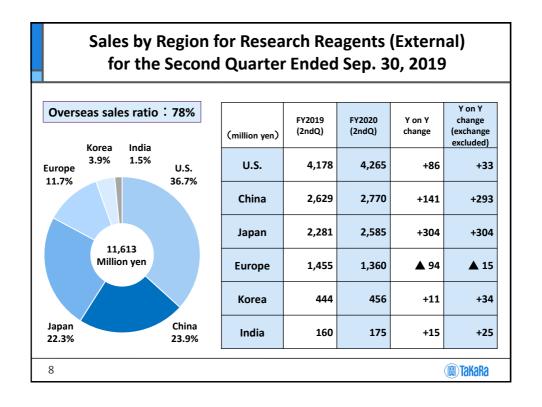
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## **Contents**

- Consolidated Quarterly Financial Results for FY2020 (For the Second Quarter Ended Sep.30, 2018)
- FY2020 Forecast
- Status Overview of Primary Project

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# **Consolidated Sales Forecast by Business Segment for FY2020**

	FY2020	previous forecast		Y on Y	
(million yen)	Forecast	Change	Ratio	Change	Ratio
Bioindustry	31,531	<b>1,771</b>	▲ 5.3%	<b>A</b> 44	▲ 0.1%
Research reagents	24,147	▲ 843	▲ 3.4%	+546	+2.3%
Scientific instruments	1,255	<b>▲</b> 853	<b>4</b> 0.5%	<b>1,315</b>	▲ 51.2%
Contract service	5,748	▲ 52	▲ 0.9%	+794	+16.0%
Other	380	<b>▲</b> 23	▲ 5.8%	<b>▲</b> 69	▲ 15.4%
Gene therapy	2,368	▲ 328	<b>12.2%</b>	<b>▲</b> 74	▲ 3.1%
Other *	-		-	<b>▲</b> 1,822	-
Net sales total	33,900	▲ 2,100	▲ 5.8%	▲ 1,941	▲ 5.4%

10 \* Former AgriBio

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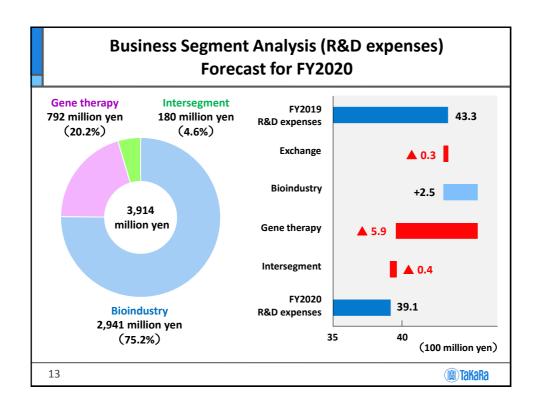
## **Consolidated Financial Forecast for FY2020**

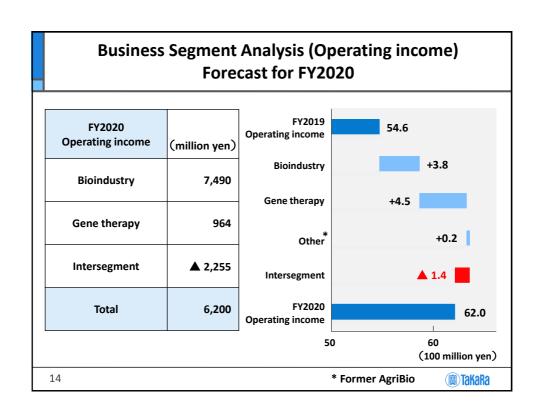
	FY2020	Compar previous		Y on Y		
(million yen)	Forecast	Change	Ratio	Change	Ratio	
Net sales	33,900	<b>▲</b> 2,100	▲ 5.8%	<b>1,941</b>	▲ 5.4%	
Cost of sales	13,050	<b>1,002</b>	<b>▲</b> 7.1%	▲ 2,104	<b>▲</b> 13.9%	
Gross profit	20,849	<b>1,097</b>	▲ 5.0%	+163	+0.8%	
SG&A expenses	14,649	<b>1,097</b>	<b>▲</b> 7.0%	▲ 572	▲ 3.8%	
Operating income	6,200	1	1	+736	+13.5%	
Ordinary income	6,350	▲ 100	▲ 1.6%	+684	+12.1%	
Net income attributable to owners of the parent	4,250	-	-	+592	+16.2%	

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**Business Segment Analysis (Net Sales)** Forecast for FY2020 FY2019 358.4 **Gene therapy Bioindustry Net sales** 2,368 million yen 31,531 million yen (7.0%) (93.0%) **4** 9.5 Exchange +9.1 **Bioindustry** ▲ 0.7 Gene therapy 33,900 million yen Other \* **18.2** FY2020 339.0 Net sales 320 350 (100 million yen) 12 \* Former AgriBio **B**TaKaRa



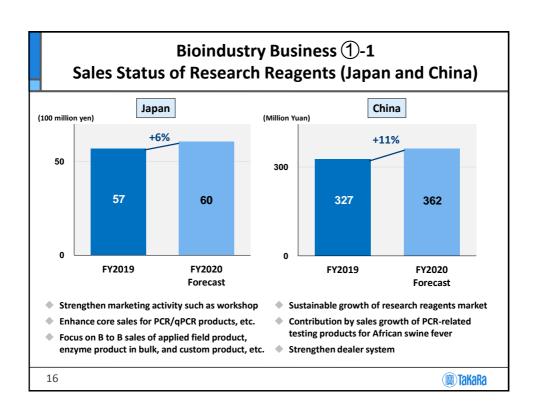


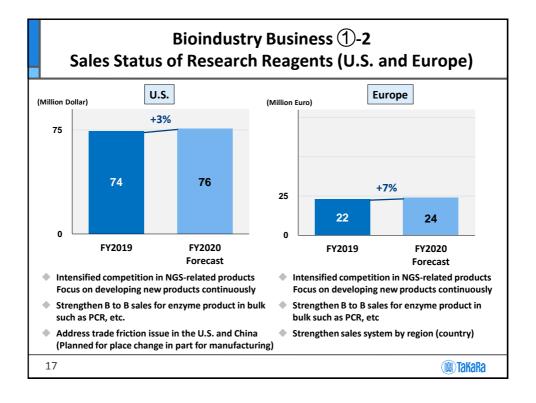
## **Contents**

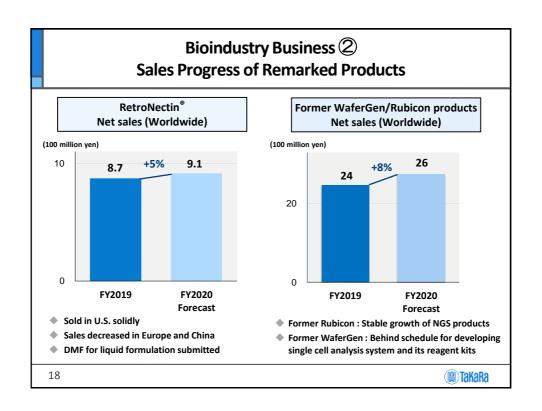
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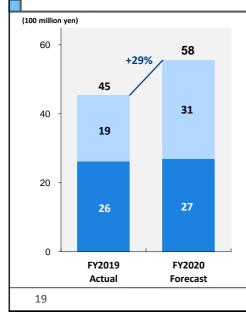
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# Bioindustry Business 3-1 CDMO Business Expansion



## Regenerative medicine products

- Scheduled for operation start of research and manufacturing facility since January 2020
- ② Develop vector manufacturing and cell processing on a high quality, large scale and high efficient production technologies

## Gene analysis / Gene testing

- Service offer meeting customer's needs in broad fields from advanced research to gene testing
- ② Aim for high-value added supply such as accuracy assurance which overcomes overseas competitors



# Bioindustry Business **3-2** CDMO Business Expansion

# Extension of Center for Gene and Cell Processing Scheduled for operation start since January 2020



- CDMO Business expansion (Regenerative medicine products-related services, gene analysis/ gene testing services)
- Strengthen manufacturing system for our own gene therapy products
- Strengthen R&D activity
- Strengthen manufacturing system for research reagents, etc.

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# Gene Therapy Business 1-1 Strategic Change in Development of Oncolytic Virus C-REV Project

## Melanoma (Development in Japan)

- In September 2019, withdrew marketing approval applied in March 2019
- Discrepancy between PMDA and Takara Bio in interpretation of requirements for conditional/term-limited authorization
- Considered comprehensively marketability (competing products and market size) in melanoma

### Pancreatic cancer (Development in Japan)

- · Phase I trial in progress
- Preliminary data about large stage presented at ESMO2019 (September 2019)
- Focus on co-development with Otsuka Pharma

### **Development in overseas**

- Co-development continuously with Dong-A ST Co., Ltd. in Korea
- Seeking partnership based on clinical data for pancreatic cancer in other areas

#### **C-REV** formulation refined

· Composition developed for formulation, available for store at 4 degree to increase preservation stability

21 ESMO: European Society for Medical Oncology



# Gene Therapy Business 1-2 **Developmental Status of C-REV Project (Pancreatic Cancer)**

## Outline of Phase I trial in Japan

- Unresectable pancreatic cancer (Stage III, IV)
- Cancer Center/National Cancer Center Hospital East and other 6 places

#### **Dose-titration stage**

1st therapy GEM/nab-PTX combination Injection to primary lesion

Preliminary data about dose-titration stage presented at ASCO-GI 2019

## Large stage

Combination with S-1 History of GEM-based therapy Stage IV hepatic metastatic

Injection to primary lesion 2<sup>nd</sup> therapy: Combination with S-1

2<sup>nd</sup> therapy:

Injection to primary lesion and hepatic metastatic lesion

n=10

Stage III non-hepatic metastatic pancreatic cancer

pancreatic cancer

1st therapy: Combination of GEM and nab-PTX Injection to primary lesion

n=10

Preliminary data about large stage presented at ESMO 2019

ASCO-GI; American Society of Clinical Oncology Gastrointenstinal Cancer Symposium 2019 Congress 22 ESMO; European Society for Medical Oncology, GEM; Gemcitabine, nab-PTX; Nab-paclitaxel



# Gene Therapy Business 2

## Developmental Status of Genetically-Engineered T cell Therapy Project

## NY-ESO-1 siTCR® (Japan)

#### Synovial sarcoma

- Phase I/II in progress in total 5 places including Mie University
- Target number cases: 8 cases
- · Aimed for early commercialization
- Designed as a product under "SAKIGAKE Designation System"

### ■ Joint/Licensing agreement

- Co-development/exclusive sales agreement with Otsuka Pharma
- Underway for preparation underway in expand indication

### NY-ESO-1 siTCR® (Canada)

#### ■ Solid cancer

- · Conducted in Princess Margaret Cancer Centre
- Target number cases: 9 cases
- Expand cohort : Under consideration for multiple administration and pretreatment

### CD19 • CAR (Japan)

#### Adult ALL (Acute lymphoblastic leukemia)

- Phase I/II in progress in total 11 places including Jichi Medical University
- · Target number cases: 21 cases
- Follow up of procedure when CRS (Cytokine release syndrome) is expressed

#### ■ Joint/License agreement

- Co-development/exclusive sales agreement with Otsuka Pharma
- Underway for Preparation underway in expand indication

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# Gene Therapy Business ③ Pipeline Status for Clinical Development

Project			Indications	Status	Partnership	
		Japan			New drug application withdrawn	Otsuka Pharma
C-REV (TBI-1401)		(TBI-1401)		Pancreatic cancer	Phase I in progress	Otsuka Pharma
virus	Nonpropriatary name : canerpaturev Trade name : EPLICANA®		Korea	All indications	In preparation	Dong-A ST Co., Ltd.
				Melanoma	Investigator initiated trial in progress	-
	CAR	CD19		Adult ALL*	Phase I/II in progress	Otsuka Pharma
	CAR	(TBI-1501)	Japan	Expand indications	In preparation	Otsuka Pharma
Engineered T cell therapy			lanan	Synovial sarcoma	Phase I/II in progress	Otsuka Pharma
шегару	siTCR <sup>®</sup>	NY-ESO-1 (TBI-1301)	Japan	Expand indications	Under review	Otsuka Pharma
			Canada	Solid cancer	Investigator initiated trial in progress	-

24 \* ALL : Acute lymphoblastic leukemia



# Focus on Creating New Modality and Developing Platform Technology

- Develop new generation CAR-T carrying signal transduction domain such as GITA and JAK/STAT, etc.
- Screening of new cancer antigen for T cell leveraging Neoantigen analysis
- Develop new virus vector for gene therapy and establish production technique on a large-scale
- Develop platform technology, aimed at improving productivity for gene-transduced cells (leading to cost down)
- Develop liquid biopsy applicable to cancer immune therapy and platform technology related to clinical sequencing

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

Previous FY2020 quantitative target (formulated in May 2017)

Net sales 38.5 billion yen Operating income 4.0 billion yen



Current FY2020 quantitative target (Revised in November 2019)

Net sales 33.9 billion yen Operating income 6.2 billion yen

### **Bioindustry**

Regenerative medicine productsrelated CDMO business holding 1<sup>st</sup> position

- Expanding CDMO business for vector manufacturing, cell processing, quality testing
- Built newly for research and manufacturing facility (Scheduled for completion in January 2020)

### **Gene Therapy**

- Approval acquisition of gene therapy products
- Withdrew new drug application of C-REV for melanoma
- Cooperated on projects for oncolytic virus and engineered T cell therapy

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## **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.

For more information: PR  ${}^{\scriptscriptstyle \bullet}$  IR Department, Takara Bio Inc.

E-mail: bio-ir@takara-bio.co.jp

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## [Reference]

## **Reference Information**

- Consolidated Sales Results by Business Segment
- Results by Business Segment
- Forecast by Business Segment for FY2020
- Forecast by Region for Research Reagents
- Results by Subsidiary
- Forecast by Subsidiary for FY2020
- Exchange Rates for the Income Statement of Overseas Subsidiaries

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						[Reference]				
	Consolidated Sales Results by Business Segment									
	(million yen)									
		FY2020	Compared with previous forecast			n Y				
		Forecast	Change	Ratio	Change	ratio				
	Bioindustry	14,406	<b>468</b>	▲ 3.1%	+90	+0.6%				
	Research reagents	11,613	<b>▲</b> 93	▲ 0.8%	+464	+4.2%				
	Scientific instruments	620	▲ 385	▲ 38.3%	<b>A</b> 770	▲ 55.4%				
	Contract service	1,961	<b>1</b> 6	▲ 0.8%	+406	+26.1%				
	Other*	210	+27	+14.8%	<b>1</b> 0	<b>4.6%</b>				
	Gene therapy	2,044	<b>A</b> 210	<b>▲</b> 9.3%	<b>1</b> 00	<b>4.7%</b>				
	Other	-	-	-	▲ 909	-				
	Net sales total	16,450	<b>▲</b> 678	<b>4.0%</b>	▲ 919	▲ 5.3%				
2	9 * Former AgriBio					<b>® TaKaRa</b>				

	Results	s by Busin	ess Segm	ent	[Reference
					(million yen
<fy2019 actual=""></fy2019>	Bioindustry	Gene therapy	Former AgriBio	Intersegment	Total
Net sales	14,316	2,144	909	0	17,370
Gross profit	8,311	1,862	147	0	10,321
SG&A expenses	5,722	664	232	1,078	7,697
R&D expenses from above	1,353	655	0	95	2,104
Operating income	2,588	1,198	▲ 85	▲ 1,078	2,623
<fy2020 forecast=""></fy2020>	Bioindustry	Gene therapy	Other	Intersegment	Total
Net sales	14,406	2,044	-	0	16,450
Gross profit	8,613	1,715	-	0	10,329
SG&A expenses	5,741	427	-	1,124	7,293
R&D expenses from above	1,382	392	-	83	1,858
Operating income	2,872	1,287	-	▲ 1,124	3,035

					[Reference]		
Forecast by Business Segment for FY2020							
			-0		(million yen)		
<fy2019 actual=""></fy2019>	Bioindustry	Gene therapy	Former AgriBio	Intersegment	Total		
Net sales	31,575	2,443	1,827	<b>▲</b> 5	35,841		
Gross profit	18,369	1,915	399	0	20,685		
SG&A expenses	11,269	1,409	429	2,114	15,221		
R&D expenses from above	2,723	1,391	0	222	4,337		
Operating income	7,100	506	▲ 29	▲ 2,114	5,463		
<fy2020 forecast=""></fy2020>	Bioindustry	Gene therapy	Other	Intersegment	Total		
Net sales	31,531	2,368	-	0	33,900		
Gross profit	19,017	1,831	-	0	20,849		
SG&A expenses	11,527	866	-	2,255	14,649		
R&D expenses from above	2,941	792	-	180	3,914		
Operating income	7,490	964	-	▲ 2,255	6,200		
					,		
31					<b>B</b> TaKaRa		

F	Forecast by Region for Research Reagents  (million yen)							
	FY2019 Actual Forecast  FY2020 Y on Y change (Exchange excluded)							
U.S.	8,230	8,287	+57	+221				
Japan	5,715	6,072	+357	+357				
China	5,470	5,659	+188	+591				
Europe	2,948	2,919	▲ 28	+191				
Korea	917	859	▲ 58	+20				
India	319	348	+28	+44				
Overseas sales	Overseas sales ratio : 75%							
32	32 III TAKARA							

[Reference] Results by Subsidiary							
(million yen)							
		FY2019	Actual	F2020	Actual		
	Number of Employee**	Net sales	Operating income	Net sales	Operating income		
Takara Bio	521	11,037	1,551	10,502	1,621		
Mizuho Norin*	0	603	▲ 75	-	-		
Takara Bio Farming Center *	0	17	4	-	-		
KINOKO CENTER KIN*	0	80	▲ 15	-	-		
Takara Bio Europe	73	1,537	78	1,509	30		
Takara Biotechnology (Dalian)	522	1,799	352	1,701	447		
Takara Biomedical Technology (Beijing)	71	2,943	532	3,018	554		
Takara Korea Biomedical	25	509	81	510	86		
DSS Takara India Pvt. Ltd.	66	167	6	182	11		
Takara Bio USA Inc.	205	5,254	465	5,274	503		
Takara Bio USA Holdings Inc	0	-	▲ 3	-	▲ 2		
* Business transferred in Mar. 2019	**As of Sep.	30, 2019					
33					<b>Takara</b>		

[Reference Forecast by Subsidiary for FY2020 (million yen)							
	FY2019	Actual	FY2020	Forecast			
	Net sales	Net sales Operating income Net sales		Operating income			
Takara Bio	21,740	2,312	21,382	2,449			
Mizuho Norin*	1,265	▲ 33	-	-			
Takara Bio Faming Center *	17	4	-	-			
KINOKO CENTER KIN*	179	▲ 10	-	-			
Takara Bio Europe	3,362	244	3,317	221			
Takara Biotechnology (Dalian)	3,805	875	3,372	953			
Takara Biomedical technology (Beijing)	6,121	1,057	6,152	1,133			
Takara Korea Biomedical	1,034	173	996	159			
DSS Takara India Pvt. Ltd.	335	5	364	26			
Takara Bio USA Inc.	11,224	1,533	11,049	1,635			
Takara Bio USA Holdings Inc	-	<b>▲</b> 5	-	▲ 5			
* Business transferred in Mar. 2019							
34 <b>III Takara</b>							

## [Reference]

## Exchanges Rates for the Income Statement of Overseas Subsidiaries

(Unit: yen)	FY2019 (2ndQ)	FY2019 (Full year)	FY2020 (2ndQ)	FY2020 (Full year)
	Actual	Actual	Actual	Forecast as of Nov. 12
US dollar	108.68	110.45	110.06	108.30
Euro	131.55	130.35	124.32	121.30
Yuan	17.09	16.71	16.20	15.60
100 Won	10.10	10.04	9.61	9.20
Rupee	1.66	1.62	1.57	1.55
Sweden Krona	12.97	12.71	11.83	11.50