

FY2019 Consolidated Financial Results

- Financial Results review
- Progress of
“Medium-Term Management Plan FY2020”

TAKARA BIO INC.
May 16, 2019

Contents

- **Consolidated Financial Results for FY2019**
- Measures of Primary Project
- Progress of
“Medium-Term Management Plan FY2020”

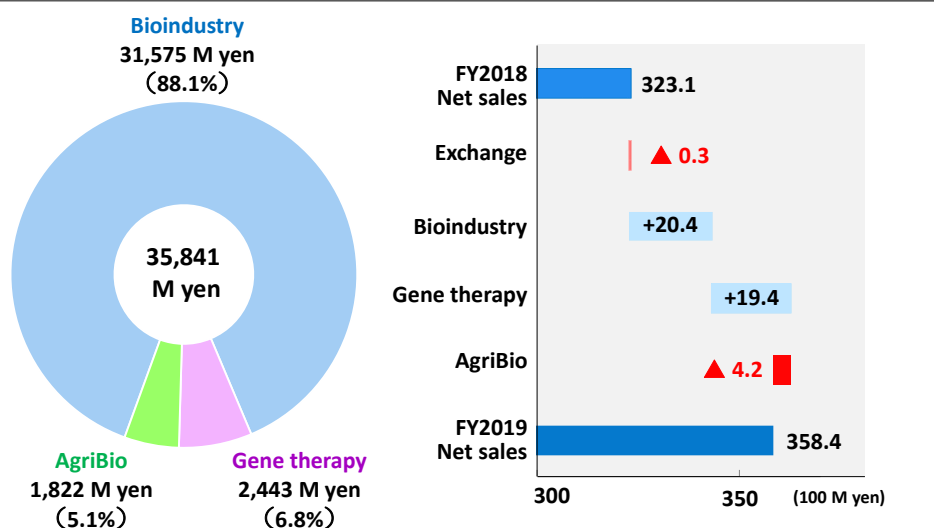
Consolidated Financial Results for FY2019

(M yen)	FY2019 Actual	Compared with previous forecast		Y on Y	
		Change	Ratio	Change	Ratio
N e t s a l e s	35,841	+ 41	+ 0.1%	+3,528	+10.9%
C o s t o f s a l e s	15,155	+ 220	+ 1.5%	+ 1,497	+ 11.0%
G r o s s p r o f i t	20,685	▲ 179	▲ 0.9%	+2,030	+10.9%
S G & A e x p e n s e s	15,221	▲ 443	▲ 2.8%	+121	+0.8%
O p e r a t i n g i n c o m e	5,463	+263	+5.1%	+1,908	+53.7%
O r d i n a r y i n c o m e	5,665	+265	+4.9%	+1,803	+46.7%
N e t i n c o m e a t t r i b u t a b l e t o o w n e r s o f t h e p a r e n t	3,657	+507	+16.1%	+1,322	+56.6%

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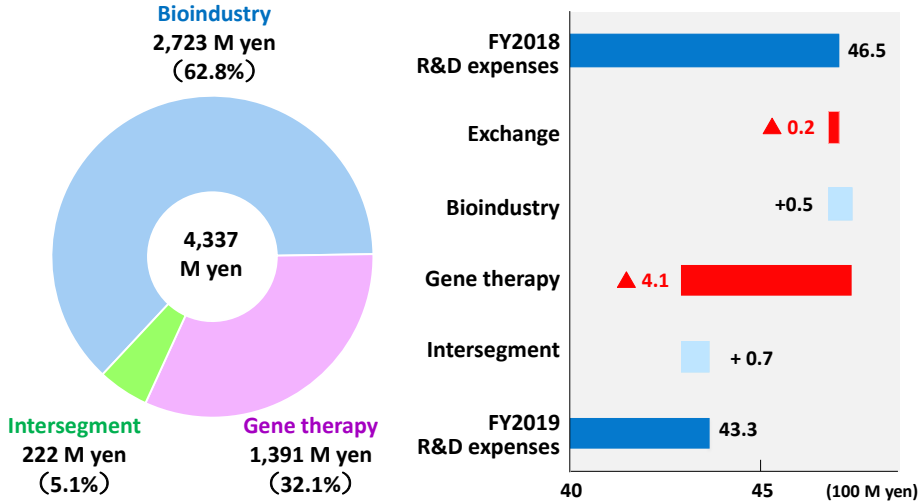
Business Segment Analysis for Net Sales (Consolidated) for the Year Ended Mar. 31, 2019



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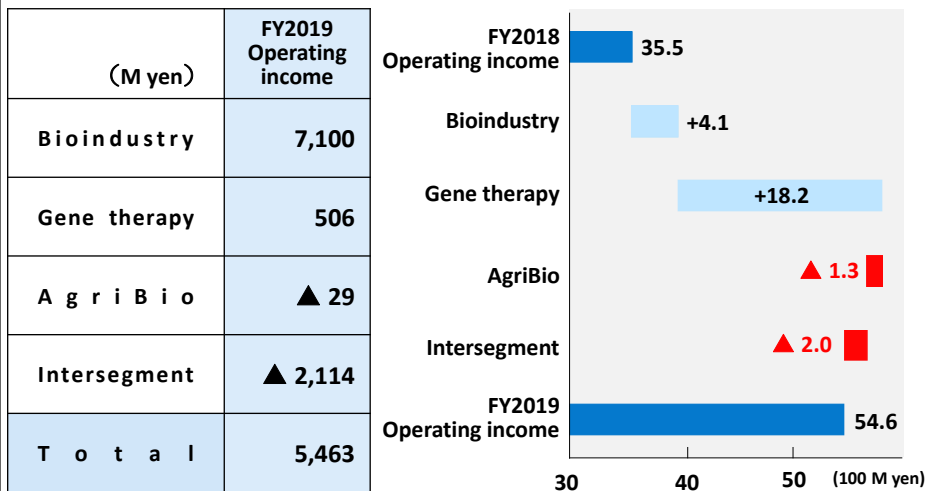
Business Segment Analysis for R&D expenses (Consolidated) for the Year Ended Mar. 31, 2019



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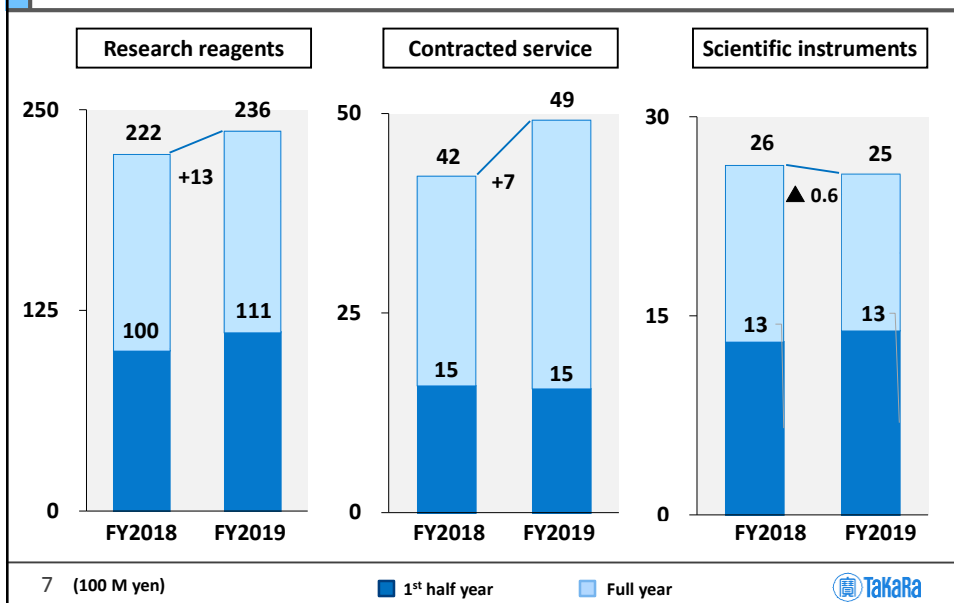
Business Segment Analysis for Operating income (Consolidated) for the Year Ended Mar. 31, 2019



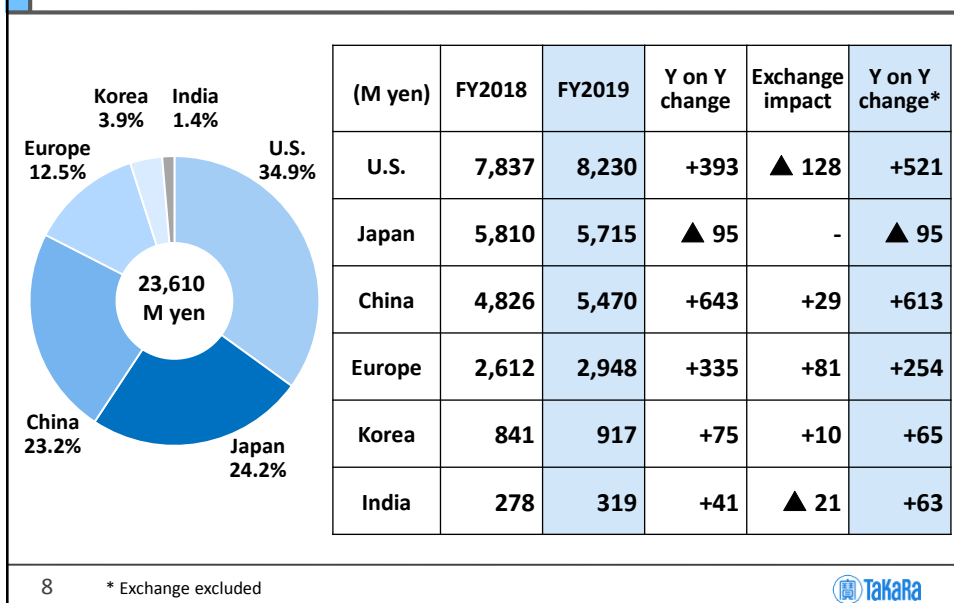
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Sales by Category in Bioindustry Business for the Year Ended Mar. 31, 2019



Sales by Region for Research Reagents (Consolidated) Overseas Sales Ratio : 76%



Overview of Business Transfer of AgriBio

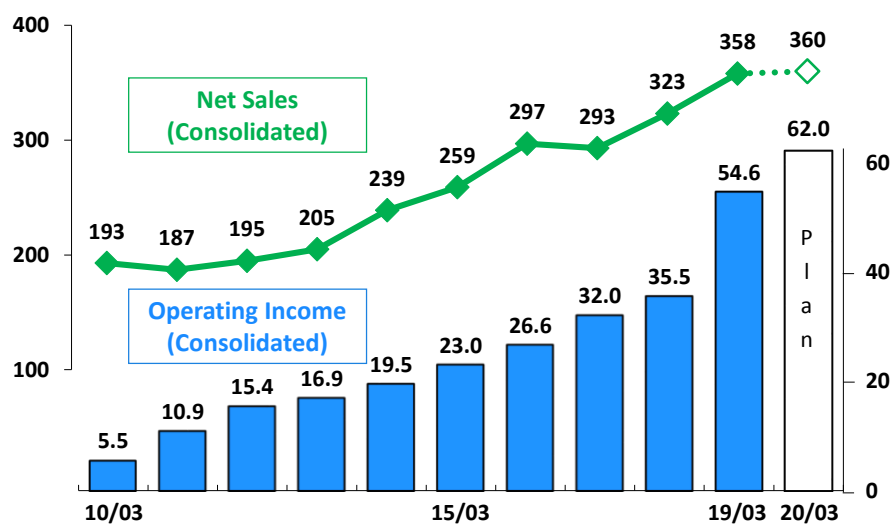
	Functional food business	Mushroom business
Successor company	Shionogi Healthcare Co., Ltd.	Yukiguni Maitake Co., Ltd.
Objective	Business divestiture due to simplified absorption-type company split (Primary asset succeeded) <ul style="list-style-type: none"> •All shares of Takara Bio Farming Center Inc. owned by Takara Bio •IP relating to functional food business 	<ul style="list-style-type: none"> •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



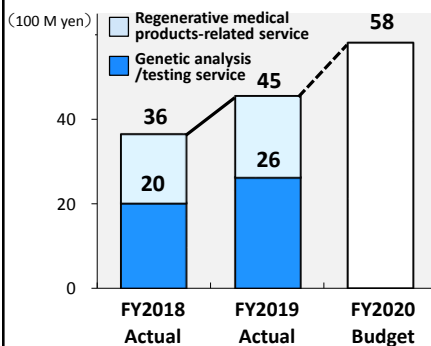
10 (100 M yen)



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- Progress of “Medium-Term Management Plan FY2020”

Bioindustry Business ① CDMO Business Expansion



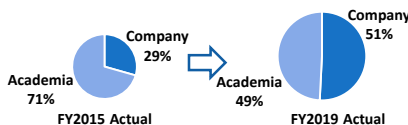
Regenerative medical products-related service Respond to increasing service orders

- 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

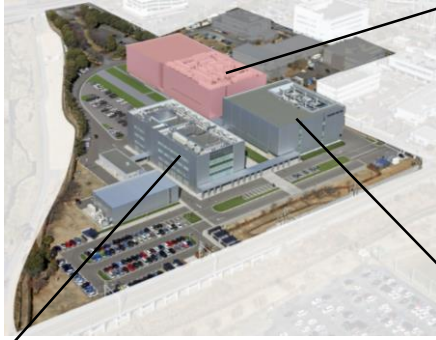
Genetic analysis/Genetic testing service Aim for high-value added supply such as accuracy assurance which overcomes competitors

- 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



Bioindustry Business ② In Construction for Research and Manufacturing Facility



New construction (About 14,500 m²)

- Plan for further expanding QC area and increasing capacity for vector manufacturing
- Make system responding flexibly to CDMO service with 4,600 m² backup space

Main research facility (Lab area about 1,200 m² on 3rd FL)

- Expand NGS area

Center for Gene and Cell Processing (About 6,700 m²)

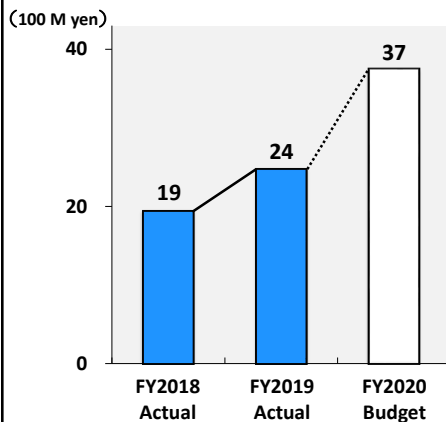
- Use continuously QC area
- Strengthen cell processing capability with additional operation in CPR at LIC, Kanagawa pref.

13 CPR : Cell Processing Room



Bioindustry Business ③ Progress of Remarketed Products (1)

Former WaferGen and Rubicon products Net sales (Worldwide)



Former WaferGen products

- ◆ Behind schedule for launching new single analysis instrument and its applicable reagents
- ◆ Retrieve the delay by launching new reagent products, especially in the U.S and Europe



New single cell analysis system
SMARTer™ ICELL8™ cx

Former Rubicon products

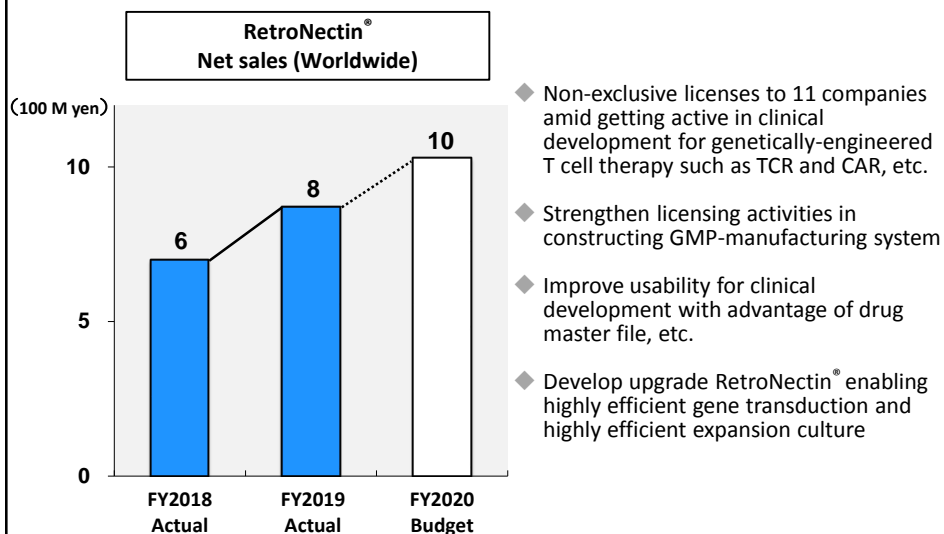
- ◆ Facilitate B to B business toward NGS service provider
- ◆ Develop application such as cell-free DNA cancer panel with advantage of ultra-low nucleic acid analysis technique

14 Rubicon ; Acquired in January 2017 WaferGen ; Acquired in March 2017



Bioindustry Business ④

Progress of Remarketed Products (2)



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Bioindustry Business ⑤

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*1	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

17 * 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)
 - Planned for presentation 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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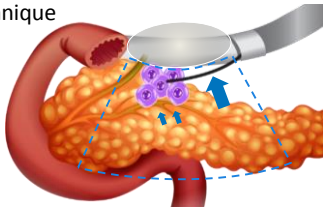


Gene Therapy Business ③

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



≥G3 adverse effects

Attributable to C-REV	1 (17%)
------------------------------	----------------

Best overall response rate (N = 6)

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

19 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

20 * 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)

- Presentation of preliminary data 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/m² x 2 days
 - ② TBI-1301 5x10⁹ 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

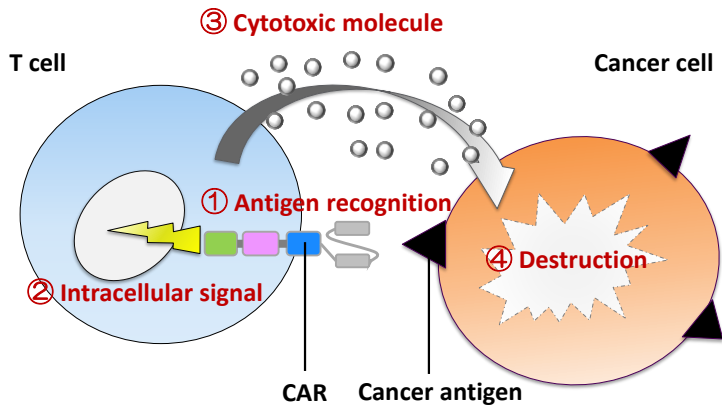
- Develop new CAR structure (intracellular domain for signal transduction such as GITR and JAK/STAT)
- Screening of new cancer antigen for T cell : Leverage Neoantigen analysis
- Develop new virus vector for gene therapy and establish production technique on a large-scale*
- Develop basic technology, 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

22 * Started AMED project “Research and development of core technologies for gene and therapy” from April 2019



Toward Developing Novel CAR Gene Therapy ①

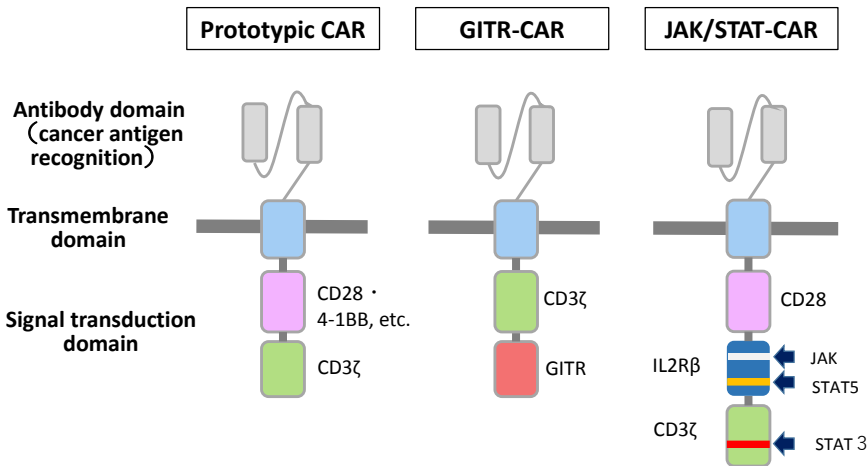
Functional mechanism of CAR gene therapy



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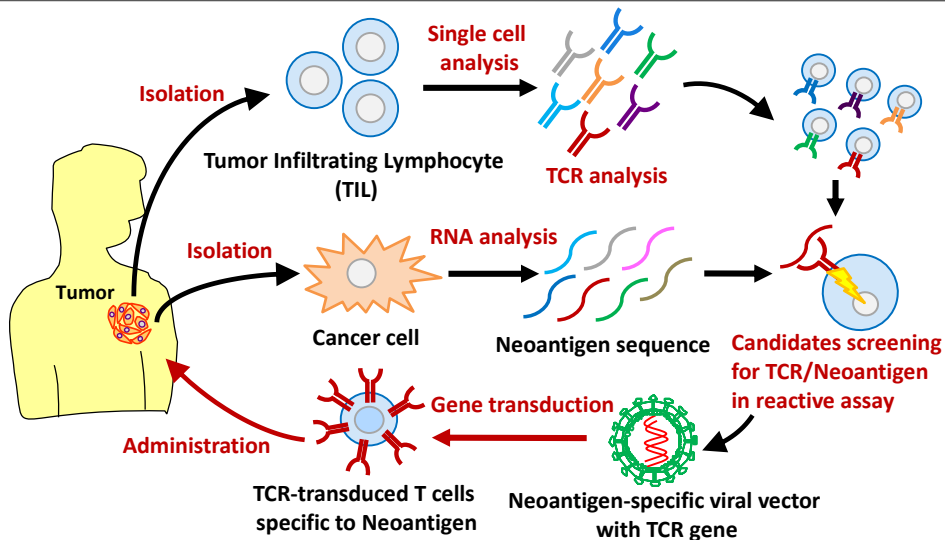
Toward Developing Novel CAR Gene Therapy ②



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Toward developing Neoantigen TCR Gene Therapy



25 TCR: T Cell Receptor



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“Medium-Term Management Plan FY2020”**

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FY2020 Budget (Consolidated)

(M yen)	FY2019 Actual	FY2020 Budget	Y on Y	
			Change	Ratio
N e t s a l e s	35,841	36,000	+158	+0.4%
C o s t o f s a l e s	15,155	14,053	▲ 1,102	▲ 7.3%
G r o s s p r o f i t	20,685	21,946	+1,261	+6.1%
S G & A e x p e n s e s	15,221	15,746	+525	+3.4%
O p e r a t i n g i n c o m e	5,463	6,200	+736	+13.5%
O r d i n a r y i n c o m e	5,665	6,450	+784	+13.9%
N e t i n c o m e a t t r i b u t a b l e t o o w n e r s o f t h e p a r e n t	3,657	4,250	+592	+16.2%
R & D e x p e n s e s	4,337	4,292	▲ 44	▲ 1.0%

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Progress of “Medium-Term Management Plan FY2020” (Formulated in May 2017) ①

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

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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

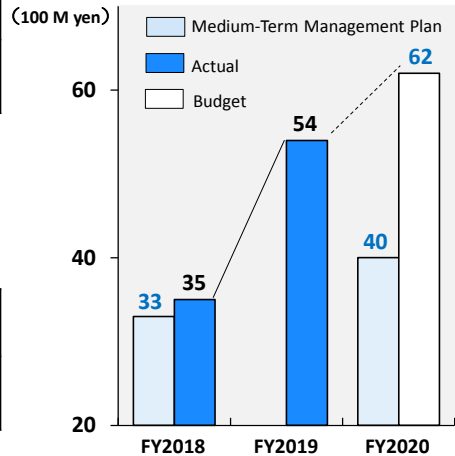


Income target revised upwardly but sales target revised downwardly due to AgriBio business transfer, etc.

FY2020 Takara Bio consolidated results

Net sales 36.0 billion yen
Operating income 6.2 billion yen

Consolidated operating income



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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 • IR Department, Takara Bio Inc.
E-mail: bio-ir@takara-bio.co.jp

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Reference Information

- FY2019 Net Sales (Consolidated)
- FY2020 Budget for Net Sales (Consolidated)
- Results by Business Segment (FY2019 Actual vs FY2020 Budget)
- Sales for Research Reagents (FY2020 Budget)
- Results by Subsidiary (FY2019 Actual vs FY2020 Budget)
- Exchange Rates for the Income Statement of Overseas Subsidiaries

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【Reference】

FY2019 Net Sales (Consolidated)


(M yen)

	FY2019 Actual	Compared with previous forecast		Y on Y	
		Change	Ratio	Change	Ratio
B i o i n d u s t r y	31,575	+93	+0.3%	+2,006	+6.8%
Research Reagents	23,601	▲ 102	▲ 0.4%	+1,393	+6.3%
Scientific instruments	2,570	▲ 17	▲ 0.7%	▲ 64	▲ 2.5%
Contracted service	4,954	+226	+4.8%	+743	+17.6%
O t h e r s	449	▲ 13	▲ 2.9%	▲ 65	▲ 12.7%
G e n e t h e r a p y	2,443	+4	+0.2%	+1,943	+388.6%
A g r i B i o	1,822	▲ 57	▲ 3.0%	▲ 421	▲ 18.8%
Functional foods	409	0	0%	▲ 283	▲ 40.9%
M u s h r o o m s	1,412	▲ 57	▲ 3.9%	▲ 137	▲ 8.9%
Net sales total	35,841	+41	0.1%	+3,528	+10.9%


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[Reference]				
FY2020 Budget for Net Sales (Consolidated)				
(M yen)				
	FY2019 Actual	FY2020 Budget	Y on Y	
			Change	Ratio
B i o i n d u s t r y	31,575	33,302	+1,727	+5.5%
Research Reagents	23,601	24,990	+1,389	+5.9%
Scientific instruments	2,570	2,108	▲462	▲18.0%
Contracted service	4,954	5,800	+846	+17.1%
O t h e r s	449	403	▲46	▲10.3%
G e n e t h e r a p y	2,443	2,697	+253	+10.4%
O t h e r s (Former AgriBio)	1,822	-	▲1,822	-
Net sales total	35,841	36,000	158	+0.4%

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[Reference]					
Results by Business Segment (FY2019 Actual vs FY2020 Budget)					
(M yen)					
<FY2019 Actual>	Bioindustry	Gene therapy	AgriBio	Intersegment	Total
Net sales	31,575	2,443	1,827	▲ 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 Budget>	Bioindustry	Gene therapy	Others	Intersegment	Total
Net sales	33,302	2,697	-	0	36,000
Gross profit	20,049	1,896	-	0	21,946
SG&A expenses	12,299	900	-	2,546	15,746
R&D expenses from above	3,041	810	-	440	4,292
Operating income	7,750	996	-	▲ 2,546	6,200

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[Reference]

Sales for Research Reagents (FY2020 Budget)

(M yen)

	FY2018 Actual	FY2020 Budget	Y on Y change	Exchange impact	Y on Y change*
U.S.	8,230	8,816	+586	▲200	+786
Japan	5,715	6,190	+475	-	+475
China	5,470	5,537	+67	▲394	+461
Europe	2,948	3,152	+204	▲134	+338
Korea	917	938	+20	▲53	+74
India	319	354	+35	▲28	+63

35 * Exchange excluded



[Reference]

Results by Subsidiary (FY2019 Actual vs FY2020 Budget)

(M yen)

	Number of employee**	FY2019 Actual		FY2020 Budget	
		Net sales	Operating income	Net sales	Operating income
Takara Bio	480	21,740	2,312	21,739	2,059
Mizuho Norin*	0	1,265	▲33	-	-
Takara Bio Faming Center *	0	17	4	-	-
KINOKO CENTER KIN *	0	179	▲10	-	-
Takara Bio Europe	71	3,362	244	4,002	518
Takara Biotechnology (Dalian)	514	3,805	875	3,910	994
Takara Biomedical technology (Beijing)	74	6,121	1,057	6,214	1,051
Takara Korea Biomedical	25	1,034	173	1,076	173
DSS Takara India Pvt. Ltd.	64	335	5	367	35
Takara Bio USA Inc.	207	11,224	1,533	12,948	1,917
Takara Bio USA Holdings Inc	0	-	▲5	-	▲3

* Business transferred in March 2019

** As of March 31, 2019

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Exchange Rates for the Income Statement of Overseas Subsidiaries

【Reference】

(Unit : yen)	FY2018	FY2019	FY2019	FY2020
	Actual	Forecast as of Jan. 30	Actual	Budget
U S d o l l a r	112.17	110.45	110.45	108.00
E u r o	126.70	130.35	130.35	125.00
Y u a n	16.62	16.71	16.71	15.60
1 0 0 W o n	9.93	10.04	10.04	9.50
R u p e e	1.73	1.62	1.62	1.50
Sweden Krona	13.15	12.71	12.71	12.40