



**Financial Results Presentation
for the Second Quarter Ended September 30, 2018**

**TAKARA BIO INC.
November 8, 2018**

Contents

- **Consolidated Quarterly Financial Results for FY2019
(For the Second Quarter Ended Sep. 30, 2018)**
- **FY2019 Forecast**
- **Status Overview of Primary Project**

Consolidated Quarterly Financial Results for FY2019 (For the Second Quarter Ended Sep. 30, 2018)

(millions of yen)

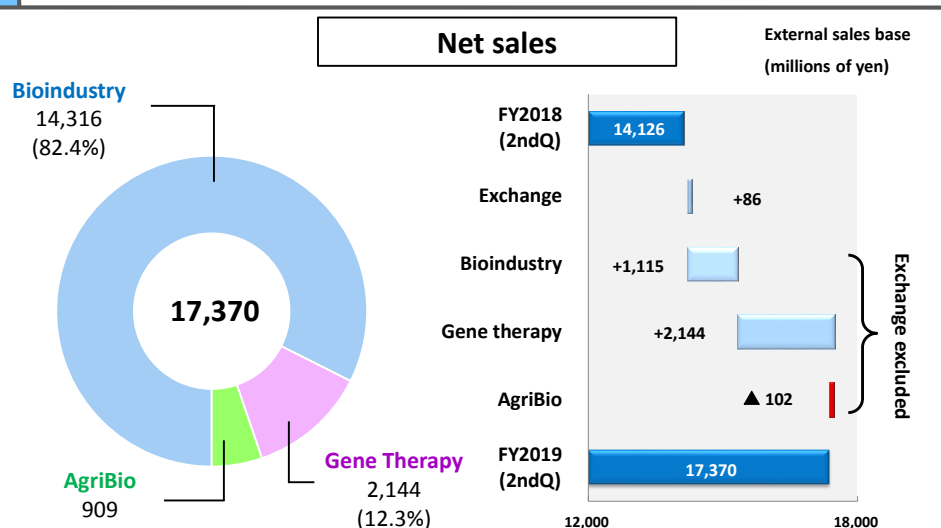
	FY2019 (2ndQ)	Compared with previous forecast		Year on year	
		Change	Ratio	Change	Ratio
Net sales	17,370	▲ 384	▲ 2.2%	+3,244	+23.0%
Cost of sales	7,049	+134	+1.9%	+1,083	+18.2%
Gross profit	10,321	▲ 519	▲ 4.8%	+2,160	+26.5%
SG&A expenses	7,697	▲ 641	▲ 7.7%	+226	+3.0%
Operating income	2,623	+122	+4.9%	+1,934	+280.9%
Ordinary income	2,669	+112	+4.4%	+1,903	+248.5%
Net income attributable to owners of the parent	1,720	+73	+4.5%	+1,418	+468.5%

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Consolidated Financial Results for the Second Quarter Ended September 30, 2018



Business Segment Analysis (Net Sales) for the Second Quarter Ended Sep. 30, 2018

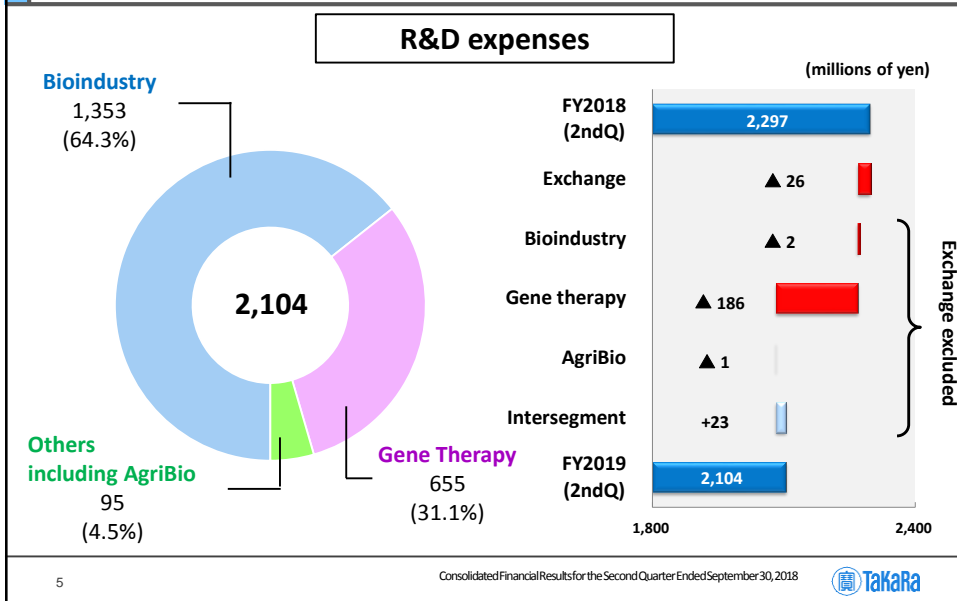


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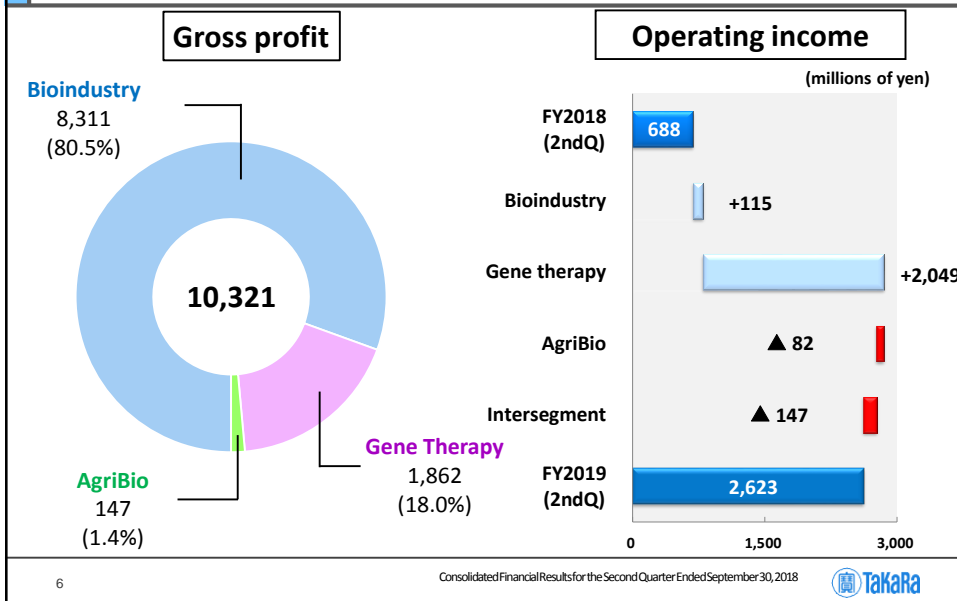
Consolidated Financial Results for the Second Quarter Ended September 30, 2018



Business Segment Analysis (R&D expenses) for the Second Quarter Ended Sep. 30, 2018

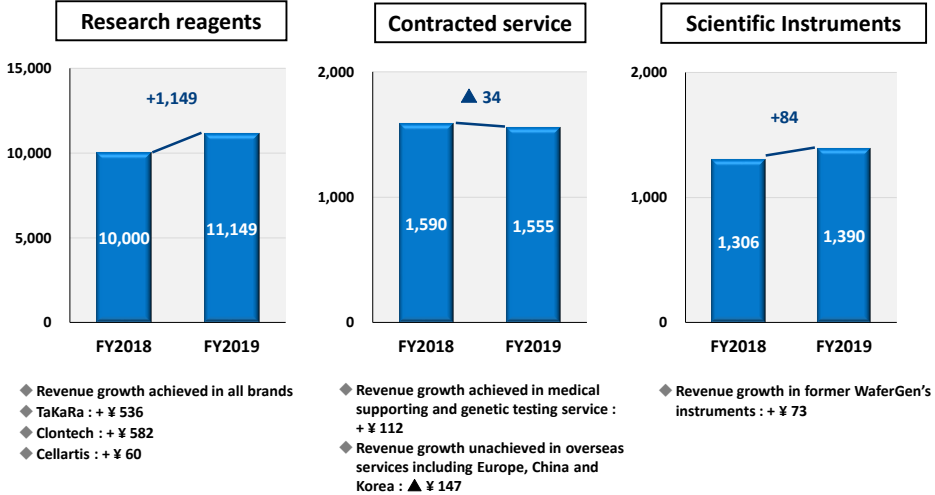


Business Segment Analysis (Gross Profit/Operating Income) for the Second Quarter Ended Sep. 30, 2018



Sales by Category in Bioindustry Business for the Second Quarter Ended Sep. 30, 2018

(millions of yen)



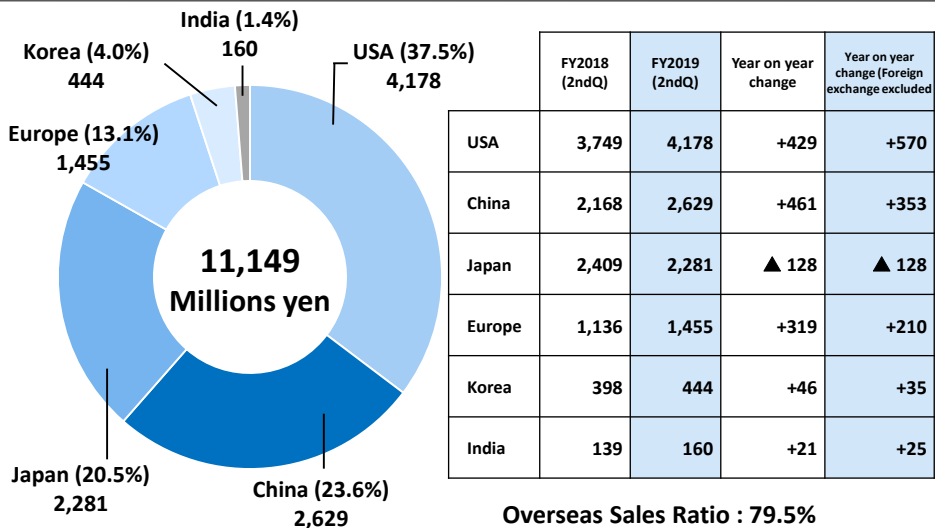
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Sales by Region for Research Reagents for the Second Quarter Ended Sep. 30, 2018

(millions of yen)



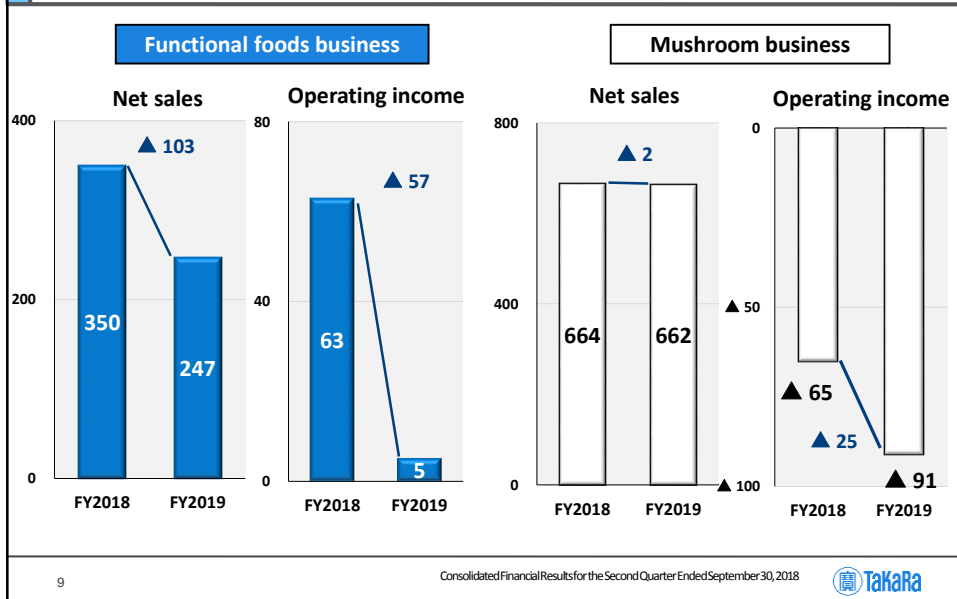
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Net Sales and Operating Income in AgriBio Business for the Second Quarter Ended Sep. 30, 2018

(millions of yen)



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Consolidated Sales Forecast by Business Segment for FY2019

(millions of yen)

	FY2019 Forecast	Compared with previous forecast		Year on year	
		Change	Ratio	Change	Ratio
Bioindustry	31,249	▲ 1,469	▲ 4.5%	+1,681	+5.7%
Research reagents	23,509	▲ 562	▲ 2.3%	+1,302	+5.9%
Scientific instruments	2,680	▲ 582	▲ 17.8%	+45	+1.7%
Contracted service	4,558	▲ 443	▲ 8.9%	+347	+8.3%
Others	500	+118	+31.0%	▲ 14	▲ 2.7%
Gene therapy	2,590	+730	+39.2%	+2,090	+418.1%
AgriBio	1,959	▲ 260	▲ 11.7%	▲ 284	▲ 12.7%
Functional foods	398	▲ 156	▲ 28.2%	▲ 294	▲ 42.5%
Mushrooms	1,560	▲ 103	▲ 6.2%	+9	+0.6%
Net sales total	35,800	▲ 1,000	▲ 2.7%	+3,487	+10.8%

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Consolidated Financial Results for the Second Quarter Ended September 30, 2018



Consolidated Financial Forecast for FY2019

(millions of yen)

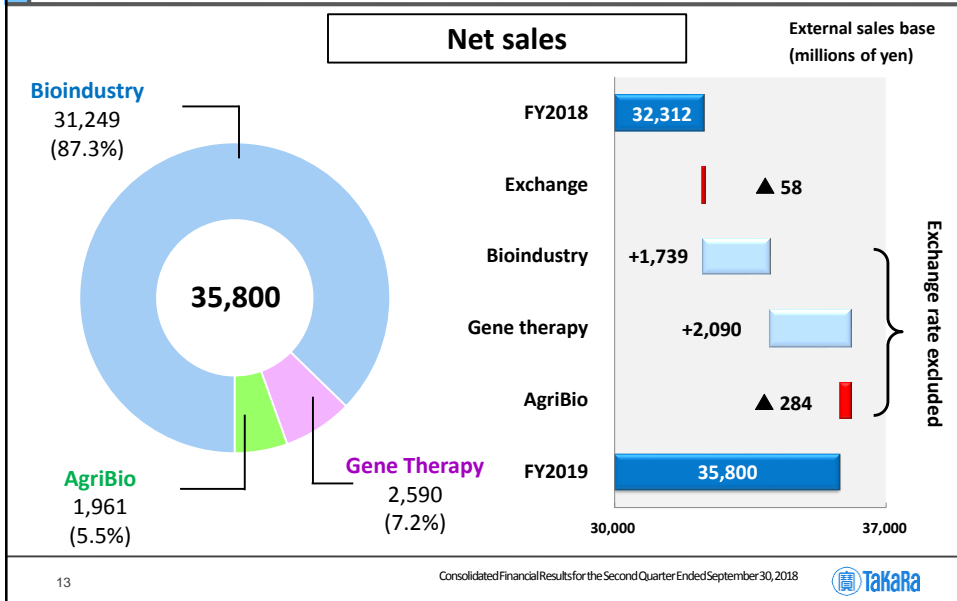
	FY2019 Forecast	Compared with previous forecast		Year on year	
		Change	Ratio	Change	Ratio
Net sales	35,800	▲ 1,000	▲ 2.7%	+3,487	+10.8%
Cost of sales	14,890	▲ 232	▲ 1.5%	+1,232	+9.0%
Gross profit	20,909	▲ 767	▲ 3.5%	+2,254	+12.1%
SG&A expenses	15,909	▲ 767	▲ 4.6%	+810	+5.4%
Operating income	5,000	-	-	+1,444	+40.6%
Ordinary income	5,200	-	-	+1,338	+34.6%
Net income attributable to owners of the parent	3,100	-	-	+764	+32.8%

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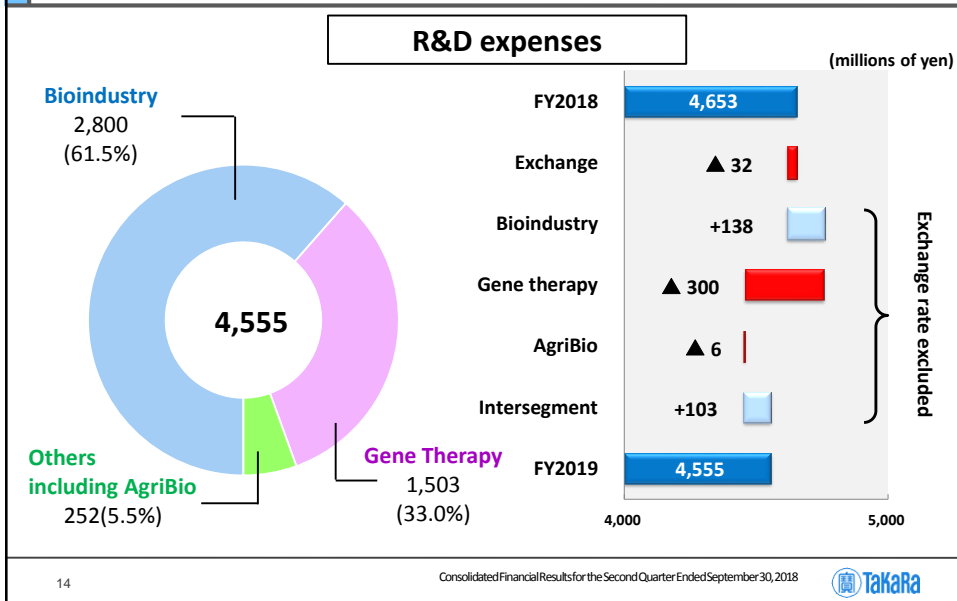
Consolidated Financial Results for the Second Quarter Ended September 30, 2018



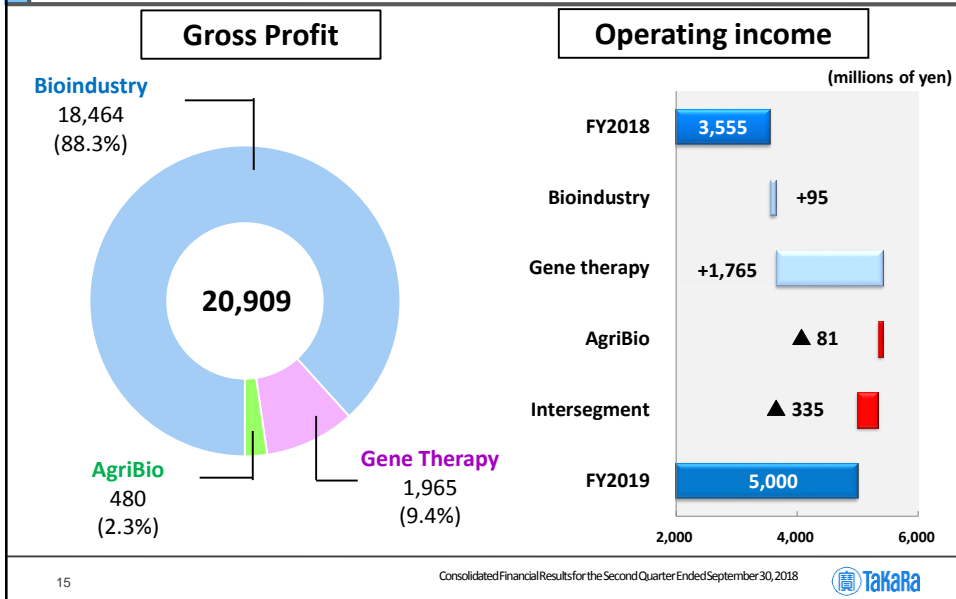
Business Segment Analysis (Net Sales) Forecast for FY2019



Business Segment Analysis (R&D expenses) Forecast for FY2019



Business Segment Analysis (Gross Profit/Operating Income) Forecast for FY2019



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(For the Second Quarter Ended Sep. 30, 2018)
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- **Status Overview of Primary Project**

Takara Bio Medium-Term Management Plan FY2020 (Revision in May 2018)

Revised Medium-Term Management Plan FY2020

FY2020 Takara Bio consolidated results
Net sales 38.5 billion yen
Operating income 6.0 billion yen

Business goal

Status of measures

Bioindustry	Regenerative medical products-related CDMO business No.1	<ul style="list-style-type: none"> In construction currently for research and manufacturing facility (Scheduled for completion in December 2019) Synergistic maximization through businesses with two overseas companies acquired
Gene therapy	Approval acquisition of gene therapy products	<ul style="list-style-type: none"> Preparation underway for C-REV approval application Clinical development of genetically-engineered T cell therapy
AgriBio	Building a platform for stable profits	<ul style="list-style-type: none"> Planned for business transfer in functional food business Unification of manufacture and sales in Mushroom business

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Consolidated Financial Results for the Second Quarter Ended September 30, 2018



Transfer of Functional Food Business to Shionogi Healthcare due to Company Split

Functional food Business

(millions of yen)	FY2016	FY2017	FY2018	FY2019 Budget
Net sales	910	842	693	398
Operating income	70	89	73	15

Transfer

Functional food Dept. (Development and manufacturing of functional food material)
Takara Bio farming Center (Cultivation of Ashitaba, Peucedanum japonicum, etc.)

Schedule

September 20, 2018 : Agreement execution
January 1, 2019 : Scheduled for completion of functional food business transfer
Scheduled for share transfer of Takara Healthcare in Takara Holdings

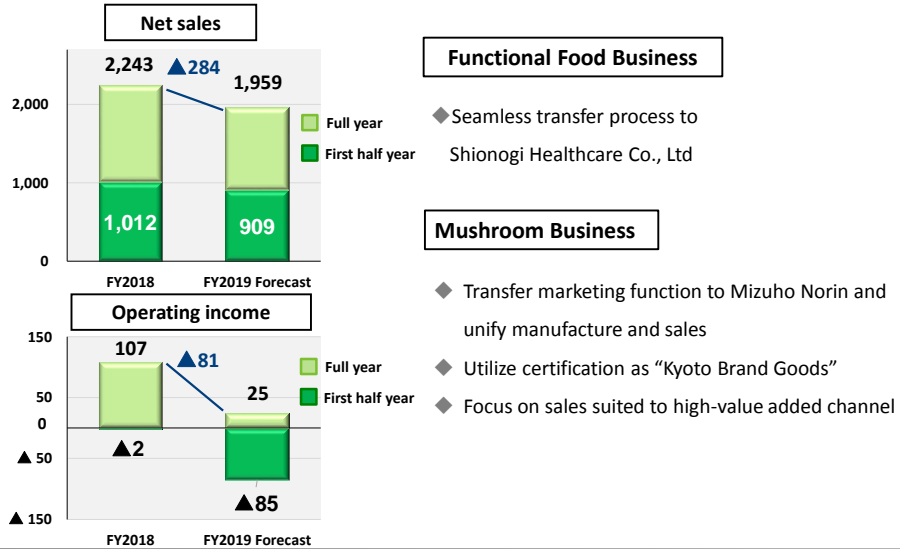
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Consolidated Financial Results for the Second Quarter Ended September 30, 2018



Measures in AgriBio Business

(millions of yen)



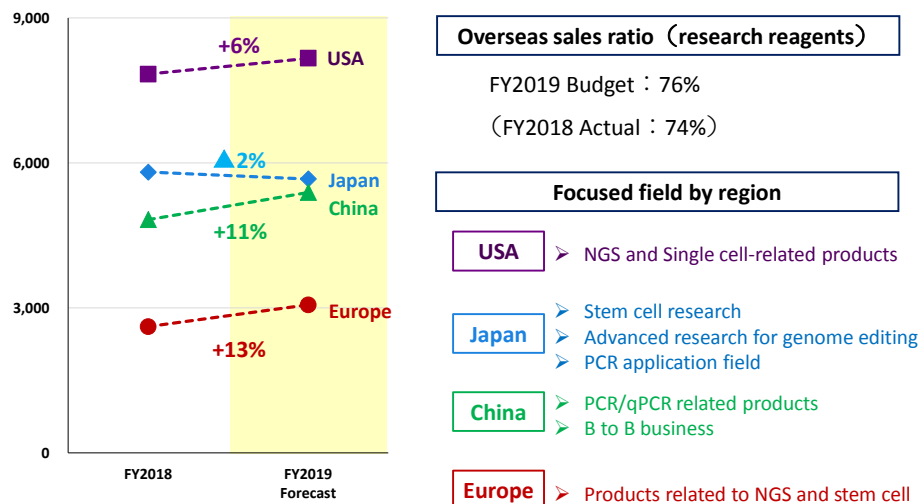
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Bioindustry Business ① Overseas Business expansion

(millions of yen)



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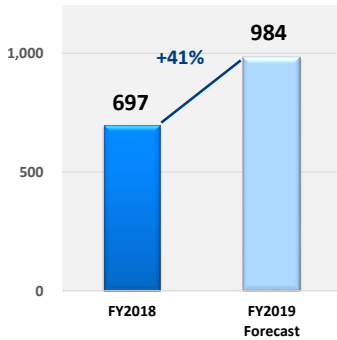
Consolidated Financial Results for the Second Quarter Ended September 30, 2018



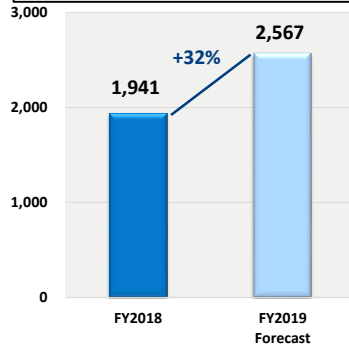
Bioindustry Business ② Progress of Remarketed Products

(millions of yen)

RetroNectin® Net sales (Worldwide)



Former WaferGen/Rubicon products Net sales (Worldwide)



- ◆ Development of gene and cell therapy products activated
- ◆ Non-exclusive licenses to 11 companies

- ◆ Former Rubicon : Facilitating growth of NGS products
- ◆ Former WaferGen : Single cell analysis instrument
New products sales delayed

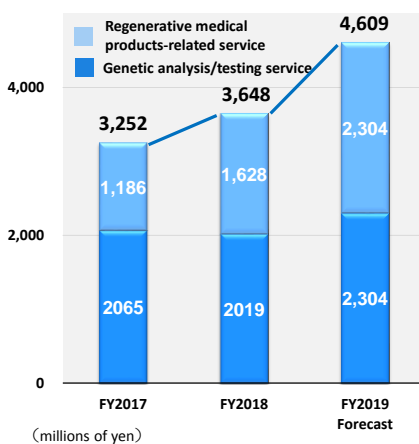
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CDMO Business Expansion

Changes in Net sales of CDMO business



Vector manufacturing/ Cell processing service

- ◆ Establish research and manufacturing facility newly for regenerative medical products (Scheduled for completion in December 2019)
- ◆ Vector manufacturing development
- ◆ Cell processing development
- ◆ Expansion of quality testing for regenerative medical products
- ◆ Provide partner with therapeutic products for a fee

Genetic analysis/ Genetic testing service

- ◆ Expansion of service menu for gene analysis such as whole genome sequencing
- ◆ Strengthen the fields of single cell analysis and clinical sequencing

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Pipeline Status for developing in Gene Therapy Business

Joint projects			Indications	Status	Partnership	
Oncolytic Virus	C-REV (TBI-1401)		Japan	Malignant melanoma	Phase II in progress Preparation underway for application	Otsuka Pharma
			Japan	Pancreatic cancer	Phase I in progress	Otsuka Pharma
			South Korea	All indications	Under review	Dong-A ST
			USA	Malignant melanoma	Phase II Investigator initiated trial in progress	Under review
Engineered T cell Therapy	siTCR™	NY-ESO-1 (TBI-1301)	Japan	Synovial sarcoma	Phase I/II in progress	Otsuka Pharma
				Indication expansion	Under review	Otsuka Pharma
			Canada	Solid cancer	Phase Ib Investigator initiated trial in progress	Preparation underway
	CAR	CD19 (TBI-1501)	Japan	Adult ALL*	Phase I/II in progress	Otsuka Pharma
				Indication expansion	Under review	Otsuka Pharma

ALL : Acute lymphoblastic leukemia

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Gene Therapy Business ①-1 Developmental Status of C-REV Project -1-

Licensing

- ◆ Otsuka Pharmaceutical, Co., Ltd
(December 15, 2016)
 - Exclusive in Japan, All indications
 - Otsuka : Clinical trial, regulatory submissions for manufacture and sales approval/safety data collection
 - Takara Bio : Manufacturing/quality control, etc.
- ◆ Dong-A ST, South Korea
(August 22, 2018)
 - Exclusive in Korea, All indications
 - Dong-A ST : Clinical trial, regulatory submissions for manufacture and sales approval/safety data collection
 - Takara Bio : Manufacturing/quality control, etc.
- ◆ Other partners
 - Continuous partner hunting

Clinical development/ Conference presentation

- ◆ Malignant melanoma (Japan)
 - Follow-up of patient administered during phase II
 - Data presentation in ESMO2018
 - Preparation underway for approval application
- ◆ Malignant melanoma (USA)
 - Combination with Nivolumab (Investigator initiated trial in progress)
- ◆ Pancreatic cancer (Japan)
 - Phase I clinical trial (Large stage) in progress
 - Planned for presentation of preliminary data (ASCO-GI 2019)

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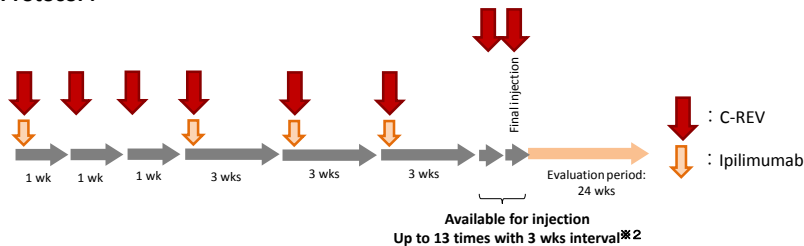
Consolidated Financial Results for the Second Quarter Ended September 30, 2018



Gene Therapy Business ①-2 Developmental Status of C-REV Project -2-

Protocol for Phase II Clinical Trial targeting malignant melanoma in Japan

- Study patient : Patient with stage IIIB-IV unresectable or metastatic melanoma
- Number of cases : 28 cases administration completed
- Trial site : National Cancer Center Hospital and Others (12 sites in total)
- Injection method/Dose : 1×10^7 TCID₅₀^{※1}/mL x 6 times (Combination with Ipilimumab)
- Protocol :



※1 : Median (50%) tissue culture infectious dose

※2 : Clinical trial treatment is acceptable, treatment reactivity is observed or SD, otherwise no critical PD in clinical practice

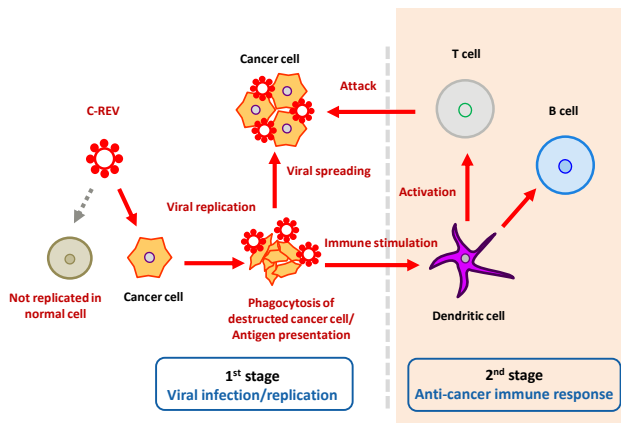
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Gene Therapy Business ①-3 Developmental Status of C-REV Project -3-

C-REV functional mechanism



Treatment effect example-based analysis

- ① Accumulation of Tumor-infiltrating lymphocyte/High expression of CD8-positive cell (Cytotoxic T cell)
- ② Elevated expression of cellular immune response-related gene

- Confirmation of viral infection and anti-cancer immune response
- Combination significance of C-REV and immune checkpoint inhibitor

※From data presented in ASCO USA in May 2018

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Gene Therapy Business ①-4 Developmental Status of C-REV Project -4-

Preliminary analysis for Phase II Clinical Trial targeting malignant melanoma in Japan

Best Overall Response N = 27

Overall response (CR + PR)	2 (7%)
Disease stability rate (CR + PR + SD)	15 (56%)
Complete response (CR)	0 (0%)
Partial response (PR)	2 (7%)
Stable disease (SD)	13 (48%)
Confirmed progressive disease (PD)	6 (22%)
Unconfirmed progressive disease (NE)	6 (22%)

- C-REV enhanced effect after anti-PD-1 antibody therapy for Japanese malignant melanoma

(Reference)

Anti-cancer effect on Ipilimumab monotherapy after anti-PD-1 antibody therapy for Japanese malignant melanoma

Overall response (CR + PR)	4%
Disease stability rate (CR + PR + SD)	16%

Journal of Dermatological Science, January 2018, 89 (1):60-66

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Gene Therapy Business ①-5 Developmental Status of C-REV Project -5-

Overview of Phase I Clinical Trial targeting pancreatic cancer in Japan

- Study patients : Unresectable pancreatic cancer (Stage III, IV)
- Practice place : Cancer Center/National Cancer Center Hospital East and other 6 places (Large stage)
- Large stage period (Scheduled) : 18 months from April 2018

<p>Dose-titration stage</p> <p>1st therapy GEM/nab-PTX combination Injection to primary lesion n=6</p> <p>Planned for presentation at the conference regarding dose-titration stage (ASCO-GI 2019)</p> <p>GEM : Gemcitabine nab-PTX : nabpaclitaxel S-1</p>		<p>Large stage ①, ② History of GEM-based therapy Stage IV hepatic metastatic pancreatic cancer</p>	<p>①2nd therapy : Combination with S-1 Injection to primary lesion n=10</p>
		<p>Large stage ③ Stage III non-hepatic metastatic pancreatic cancer</p>	<p>②2nd therapy : Combination with S-1 Injection to primary lesion and hepatic metastatic lesion n=10</p>
			<p>③1st therapy : Combination of GEM and nab-PTX Injection to primary lesion n=10</p>

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Gene Therapy Business ②-1 Status of Engineered T cell Therapy Project -1-

NY-ESO-1 siTCR™ (Japan)

- Synovial sarcoma
 - Mie University, National Cancer Center, etc.
 - Phase I/II trial in progress in total 5 places
 - Target number of cases : 8 cases
 - Product designation under "SAKIGAKE Designation system"
- Joint/Licensing agreement
 - Co-development/exclusive sales agreement with Otsuka Pharma (April 9, 2018)
- Expansion of indication
 - Under review for trial start after next year

NY-ESO-1 siTCR™ (Canada)

- Solid cancer
 - Conducted in Princess Margaret Cancer Centre
 - Target number of cases : 9 cases in progress
 - **Planned for presentation of preliminary data in 2018 SITC**
 - **Planned for presentation in 2019 ASCO**

CD19 • CAR

- Adult ALL^{※1} (Japan)
 - Jichi Medical University and others (5 sites in total)
 - Conducted in phase I/II trial
 - Target number of cases : 21 cases
 - Follow up of procedure when CRS is expressed^{※2}
 - Preparation underway for Orphan drug application
- Joint/Licensing agreement
 - Co-development/exclusive sales agreement with Otsuka Pharma (April 9, 2018)
- Expansion of indication
 - Preparation underway for trial start after next year

※1 ALL : Acute lymphoblastic leukemia
 ※2 CRS : Cytokine release syndrome

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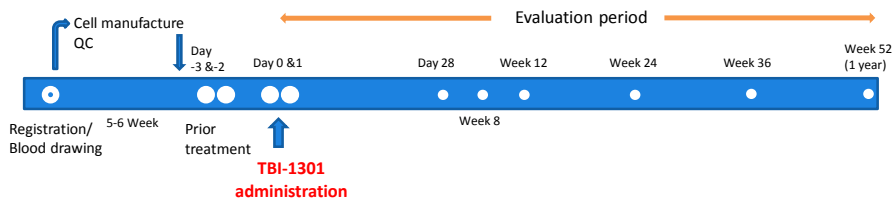
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Gene Therapy Business ②-2 Status of Engineered T cell Therapy Project -2-

Plan for NY-ESO-1 • siTCR™ Phase I/II Clinical Trial targeting pancreatic cancer in Japan

- Study patient : HLA-A*02:01 or HLA-A*02:06 positive and tumor-specific NY-ESO-1 antigen expressing patients with unresectable or relapsed synovial sarcoma
- Target number of cases : 8 cases
- Trial site : Sapporo Medical University Hospital, National Cancer Center Hospital, Mie University Hospital, Osaka National Hospital, Kyushu University Hospital
- Administration plan/Dose : TBI-1301 5×10^9 cells (2.5×10^9 cells x 2 days)
- Prior treatment : cyclophosphamide 750 mg/m^2 x 2 days
- Protocol :



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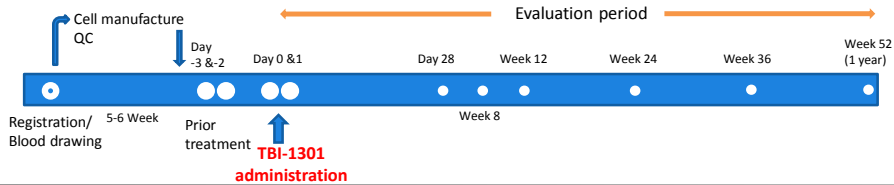
Consolidated Financial Results for the Second Quarter Ended September 30, 2018



Gene Therapy Business ②-3 Status of Engineered T cell Therapy Project -3-

Plan for CD19 • CAR Phase I/II Clinical Trial targeting adult ALL in Japan

- Study patient : Joint Phase I/II clinical trial (TBI-1501) with other facilities for patients targeting relapsed or refractory CD19-positive B cell acute lymphoblastic leukemia
- Target number of cases : 21 cases
- Trial site : Jichi Medical University, Tokyo University, Mie University, Hokkaido University, Kyushu University
- TBI-1501 administration method/Dose :
Phase I trial period : 0.3 ~ 3 x 10⁶ cells/kg in total during 2 consecutive days
Phase I trial period : Dose recommended during phase I trial
- Prior treatment : cyclophosphamide 1,000 mg/m²/day x 2 days
- Protocol :



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Consolidated Financial Results for the Second Quarter Ended September 30, 2018



Toward establishing gene therapy products as medical modality ① Manufacturing Method of Virus Vector for Gene Therapy on a Large Scale

Participation in AMED project “Research and development of core technologies for gene and therapy”

【Project outline】

Title name	Platform for manufacturing and technology development of gene cell therapeutic vector
Representative institution	Manufacturing Technology Association of Biologics/Osaka University
Period	October 2018 – March 2024 (Scheduled)
Chief Sub-project Leader	Takashi Okada, MD, Ph.D (Nippon Medical School/Manufacturing Technology Association of Biologics) Junichi Mineno, Ph.D (Takara Bio/Manufacturing Technology Association of Biologics)
R&D expenses	About 700 million (scheduled for first fiscal year)
Technology development facility (Centralized R&D)	Takara Bio facility (1 st floor of two-story building, Total area about 1,000 m ² ; Kusatsu, Shiga)

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Consolidated Financial Results for the Second Quarter Ended September 30, 2018



Issue on commercialization of Gene Therapy Products ② Establishment of Manufacturing Method for Gene-transduced cells on a Large-Scale

Utilization of Takara Bio's proprietary RetroNectin[®] technique

- High efficiency gene transduction method
- High efficiency lymphocyte propagation method

siTCR[™] technique

- Efficient manufacture of gene transduced cells using siTCR[®] technique minimizing endogenous TCR expression

Manufacturing of regenerative medical products and quality control complied with GMP/GCTP

- Knowhow accumulation such as quality testing for processed cells
- Utilization of large-scale facility for genetic analysis
- In construction currently for research, manufacturing facility and quality testing for regenerative medical products (Scheduled for operation in December 2019)

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New Creation of Cancer Immuno-gene Therapy

TCR/CAR Neo-antigen

- Joint research for antigen screening targeted with Tokyo University
- Joint research for development of new CAR therapy with University/Princess Margaret Cancer Center in Canada

Clinical sequencing

- Utilization of NGS-related technique obtained via CDMO business including large-scale genetic analysis
- Partnership with with Osaka University Hospital/Clinical testing laboratory

Liquid biopsy

- Utilization of ultralow input nucleic analysis technique obtained via product development in former Rubicon, former WaferGen and Clontech brands

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Consolidated Financial Results for the Second Quarter Ended September 30, 2018



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

Reference Information

- **Consolidated Sales Results by Business Segment**
(For the Second Quarter Ended Sep. 30, 2018)
- **Forecast by Subsidiary**
(FY2019 Forecast vs FY2018 Actual)
- **Forecast by Business Segment (FY2019 Forecast vs FY2018 Actual)**
- **Forecast by Region for Research Reagents**
(FY2019 Forecast vs FY2018 Actual)
- **Exchange Rates for the Income Statement of Overseas Subsidiaries**

Consolidated Sales Results by Business Segment [Reference]

(For the Second Quarter Ended Sep. 30, 2018)

(millions of yen)

	FY2019 (2ndQ)	Compared with previous forecast		Year on year	
		Change	Ratio	Change	Ratio
Bioindustry	14,316	▲ 647	▲ 4.3%	+1,202	+9.2%
Research reagents	11,149	▲ 363	▲ 3.2%	+1,149	+11.5%
Scientific instruments	1,390	▲ 127	▲ 8.4%	+84	+6.5%
Contracted service	1,555	▲ 176	▲ 10.2%	▲ 34	▲ 2.2%
Others	220	+20	+10.2%	+3	+1.7%
Gene therapy	2,144	+344	+19.1%	+2,144	-
AgriBio	909	▲ 81	▲ 8.2%	▲ 102	▲ 10.2%
Functional foods	247	▲ 9	▲ 3.7%	▲ 103	▲ 29.5%
Mushrooms	662	▲ 72	▲ 9.8%	+0	+0.1%
Net sales total	17,370	▲ 384	▲ 2.2%	+3,244	+23.0%

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Forecast by Subsidiary [Reference]

(FY2019 Forecast vs FY2018 Actual)

(millions of yen)


	Number of employee**	FY2018 Actual		FY2019 Forecast	
		Net sales	Operating income	Net sales	Operating income
Takara Bio	480	20,976	900	21,538	1,709
Mizuho Norin	37	729	28	1,452	6
Takara Bio Farming Center	-	26	9	17	2
KINOKO CENTER KIN	9	197	4	210	4
Takara Bio Europe SAS*	46	2,740	245	3,266	412
Takara Bio Europe AB*	23	511	▲ 75	514	▲ 73
Takara Biotechnology (Dalian) *	509	3,613	884	3,855	844
Takara Biomedical Technology (Beijing) *	75	5,448	655	6,031	1,024
Takara Korea Biomedical *	25	998	148	1,032	166
DSS Takara India Pvt. Ltd. *	67	336	▲ 14	331	11
Takara Bio USA Inc. *	217	10,725	1,122	11,386	1,504
Takara Bio USA Holdings Inc*	0	-	▲ 50	-	▲ 6

** As of Sep. 30, 2018


* Financial report from January to December

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Forecast by Business Segment (FY2019 Forecast vs FY2018 Actual)					[Reference]
(millions of yen)					
<FY2018 Actual>	Bioindustry	Gene therapy	Agribio	Intersegment	Total
Net sales	29,568	500	2,251	▲ 7	32,312
Gross profit	17,553	500	601	0	18,655
Selling, general and administrative expenses	10,870	1,822	494	1,912	15,099
Operating income from above	2,693	1,804	6	148	4,653
Operating income	6,683	▲ 1,322	107	▲ 1,912	3,555
<FY2019 Forecast>	Bioindustry	Gene therapy	Agribio	Intersegment	Total
Net sales	31,249	2,590	1,961	▲ 2	35,800
Gross profit	18,464	1,965	480	0	20,909
Selling, general and administrative expenses	11,685	1,522	455	2,247	15,909
Operating income from above	2,800	1,503	0	252	4,555
Operating income	6,778	442	25	▲ 2,247	5,000

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Forecast by Region for Research Reagents (FY2019 Forecast vs FY2018 Actual)					[Reference]
(millions of yen)					
	FY2018 Actual	FY2019 Forecast	Year on year change	Year on year change (Foreign exchange excluded)	
Japan	5,810	5,669	▲ 141	-	
USA	7,837	8,164	+327	▲ 161	
Europe	2,612	3,061	+448	+98	
China	4,826	5,391	+564	+25	
Korea	841	907	+66	+6	
India	278	314	+36	▲ 21	

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Exchanges Rates for the Income Statement of Overseas Subsidiaries

[Reference]

(Unit : yen)	FY2018 (2ndQ)	FY2018 (Full year)	FY2019	FY2019 (2ndQ)	FY2019 (Full year)
	Actual	Actual	Forecast as of May 11	Actual	Forecast as of Nov. 6
US dollar	112.34	112.17	111.00	108.68	110.00
Euro	121.66	126.70	131.00	131.55	131.00
Yuan	16.39	16.62	16.40	17.09	16.70
100 Won	9.85	9.93	9.80	10.10	10.00
Rupee	1.71	1.73	1.70	1.66	1.62
Sweden Krona	12.68	13.15	13.80	12.97	12.70