

A large, colorful mosaic map of China, composed of numerous small, irregular pieces of glass, stone, and shell in various colors like red, blue, green, yellow, and grey, set against a light beige background.

Overview of Financial Results for FY2017

CMIC HOLDINGS Co., Ltd.
November 14, 2017



FY17 Financial highlights

(October 1,2016-September 30,2017)



CMIC HOLDINGS Co., Ltd.
Wataru Mochizuki, CFO

Business segments and group companies

Blue indicates overseas.
*indicates affiliated company

Segment	Products and services	CMIC Group companies (as of end of Sep. 2017)
CRO Business	Services related to pharmaceutical development support, analytical chemistry services, and healthcare for pharmaceutical companies, and BPO and personnel services for the pharmaceutical industry	CMIC HOLDINGS Co., Ltd. CMIC Co., Ltd. CMIC-PMS Co., Ltd. CMIC ShiftZero K.K. CMIC Korea Co., Ltd. CMIC ASIA-PACIFIC, PTE. LTD. CMIC ASIA PACIFIC (MALAYSIA) SDN. BHD. CMIC Asia-Pacific (Hong Kong) Limited CMIC (Beijing) Pharmaceutical Services Co., Ltd. CMIC (Beijing) Co., Ltd. CMIC Pharma Science Co., Ltd. CMIC, INC. CMIC (Suzhou) Pharmaceutical Technology Co., Ltd. CMIC Career Co., Ltd.
CDMO Business	Services related to drug formulation development and manufacturing support, from formulation design to investigational new drug manufacturing to commercial production of ethical drugs and nonprescription drugs for pharmaceutical companies	CMIC CMO Co., Ltd. CMIC CMO Korea Co., Ltd. CMIC CMO USA Corporation CMIC JSR Biologics Co., Ltd.*
CSO Business	Services provided to pharma companies related to sales & marketing support	CMIC Ashfield Co., Ltd. MDS-CMG, Inc.*
Healthcare Business	Support services primarily for medical institutions and treating, maintaining, and promoting the health of patients and general consumers, such as SMO services and healthcare information services	Site Support Institute Co., Ltd. CMIC Healthcare Co., Ltd. CMIC VIETNAM COMPANY LIMITED
IPM Business	New business solutions provided to pharmaceutical companies that combine marketing authorization licensing and value chains. At the present stage, we are delivering development and marketing services for orphan drugs and diagnostics.	CMIC HOLDINGS Co., Ltd. CMIC CMO Co., Ltd. OrphanPacific, Inc.

● As of October 1, 2016, CMIC BS Co., Ltd., changed its trade name to CMIC Career Co., Ltd., and its segment from CSO business to CRO business.

● As of October 1, 2016, we changed segment names from CMO business to CDMO business, and from IPD business to IPM business.

● As of April 1, 2017, Healthclick Co., Ltd., changed its trade name to CMIC Healthcare Co., Ltd.

Summary of FY2017

Execution of Project Phoenix

- ▶ Established the management system for agile management
- ▶ Received more orders for PVC model projects
- ▶ Won new projects that use IPM platform

CRO Business

- ▶ Enhanced the support system in the field of regenerative medicine
- ▶ Established a joint venture with Fosun Pharma group in Suzhou, China that provides support for generic drug filing

CDMO Business

- ▶ Strategic capital investment, construction of a new injection building
- ▶ Increased order for contract manufacturing of generic drugs

CSO Business

- ▶ Started offering services in the Medical Affairs arena

Healthcare Business

- ▶ Significant recovery of SMO business

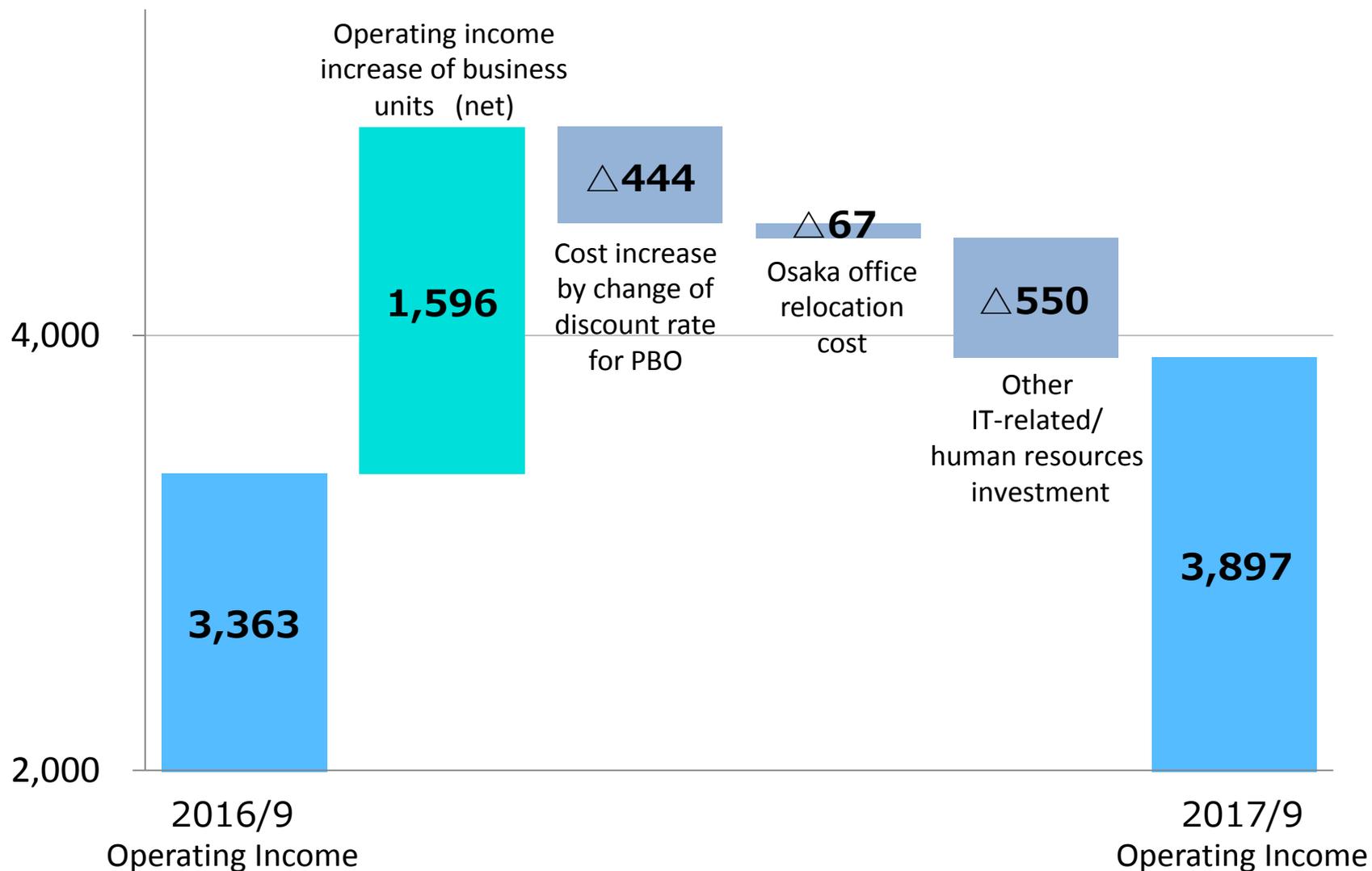
IPM Business

- ▶ Increased sales of orphan drugs, launched DIAZOXIDE Capsules 25 mg "MSD"

Consolidated income statement (overview)

	2016/9		2017/9		YoY gap (¥ millions)	Percent change (%)
	Amount	Composition ratio	Amount	Composition ratio		
	(¥ millions)	(%)	(¥ millions)	(%)		
Sales	62,039	100.0	65,282	100.0	3,242	5.2
Operating income	3,363	5.4	3,897	6.0	533	15.9
Ordinary profit	2,989	4.8	3,732	5.7	743	24.9
Profit attributable to owners of parent	878	1.4	1,550	2.4	671	76.4
Earnings per share	¥47.00		¥82.90			

Operating income YoY gap analysis



Breakdown of Non-operating income and expenses /Extraordinary losses

(¥ millions)

	2016/9	2017/9		2016/9	2017/9
Non-operating income	131	168	Extraordinary losses	389	463
Foreign exchange gains	—	96	Provision of allowance for doubtful accounts *	241	310
Interest income	31	16	Loss on sales of non-current assets	—	27
Rent income	16	8	Loss on retirement of non-current assets	45	125
Compensation income	21	—	Impairment loss	11	—
Other	60	47	Compensation expenses	90	—
Non-operating expenses	505	332	Other	1	—
Interest expenses	143	121			
Share of loss of entities accounted for using equity method	108	147			
Foreign exchange losses	186	—			
Other	66	63			

*Allowance for doubtful accounts was booked for business in Vietnam

Sales & Operating income by segment

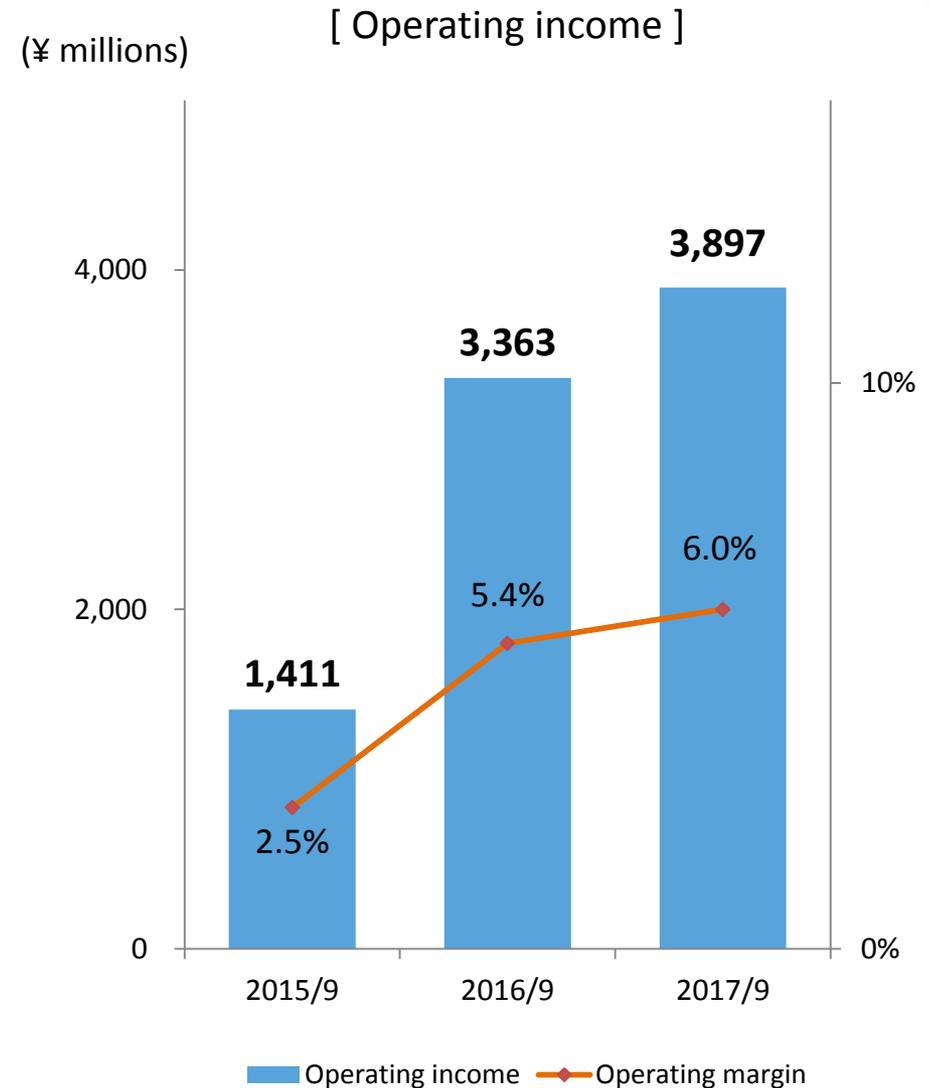
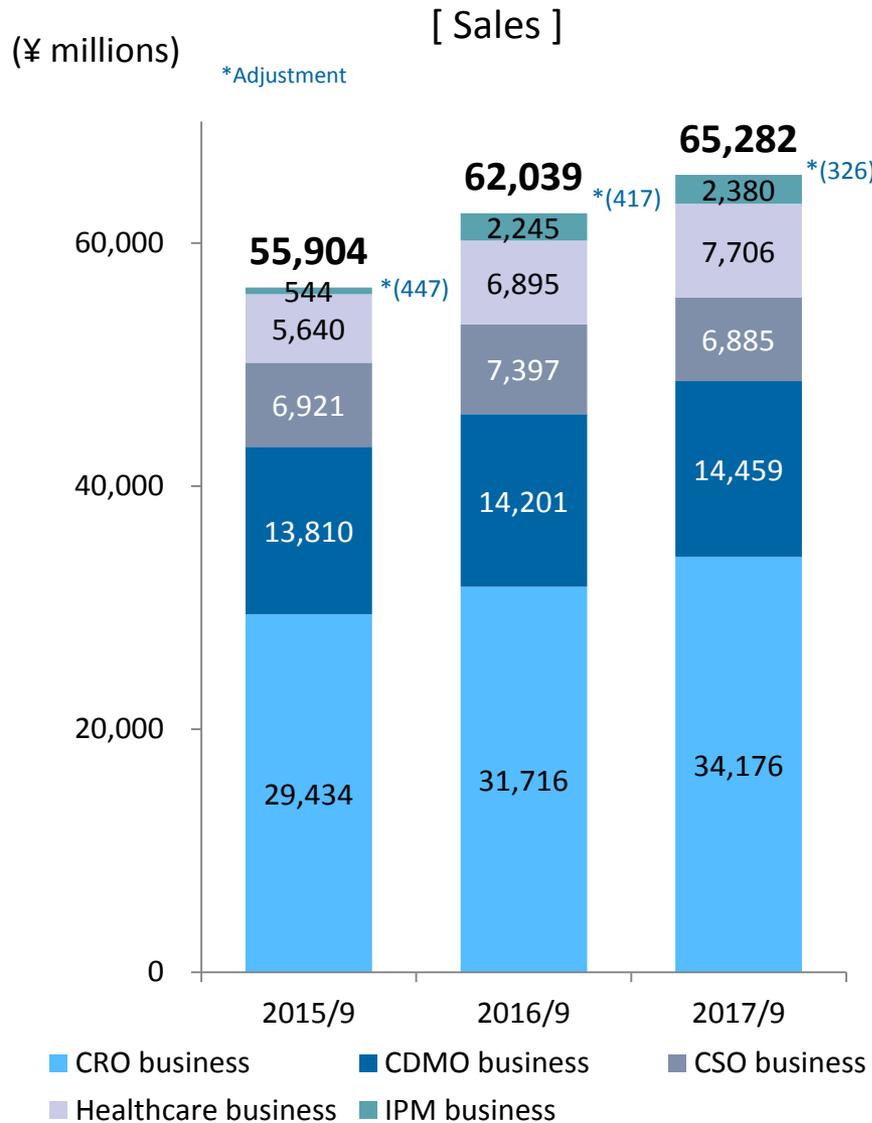
		2016/9	2017/9	Change	Percent
		Amount (¥ millions)	Amount (¥ millions)	(¥ millions)	change (%)
CRO Business	Sales	31,716	34,176	2,459	7.8
	Operating income	5,193	5,844	651	12.5
CDMO Business	Sales	14,201	14,459	257	1.8
	Operating income	293	462	168	57.6
CSO Business	Sales	7,397	6,885	(511)	(6.9)
	Operating income	452	415	(37)	(8.3)
Healthcare Business	Sales	6,895	7,706	810	11.8
	Operating income	172	988	816	474.2
IPM Business	Sales	2,245	2,380	135	6.1
	Operating income	(228)	(627)	(399)	-
Adjustments	Sales	(417)	(326)	91	-
	Operating income	(2,520)	(3,186)	(665)	-
Consolidated	Sales	62,039	65,282	3,242	5.2
	Operating income	3,363	3,897	533	15.9

Orders received / Backlog

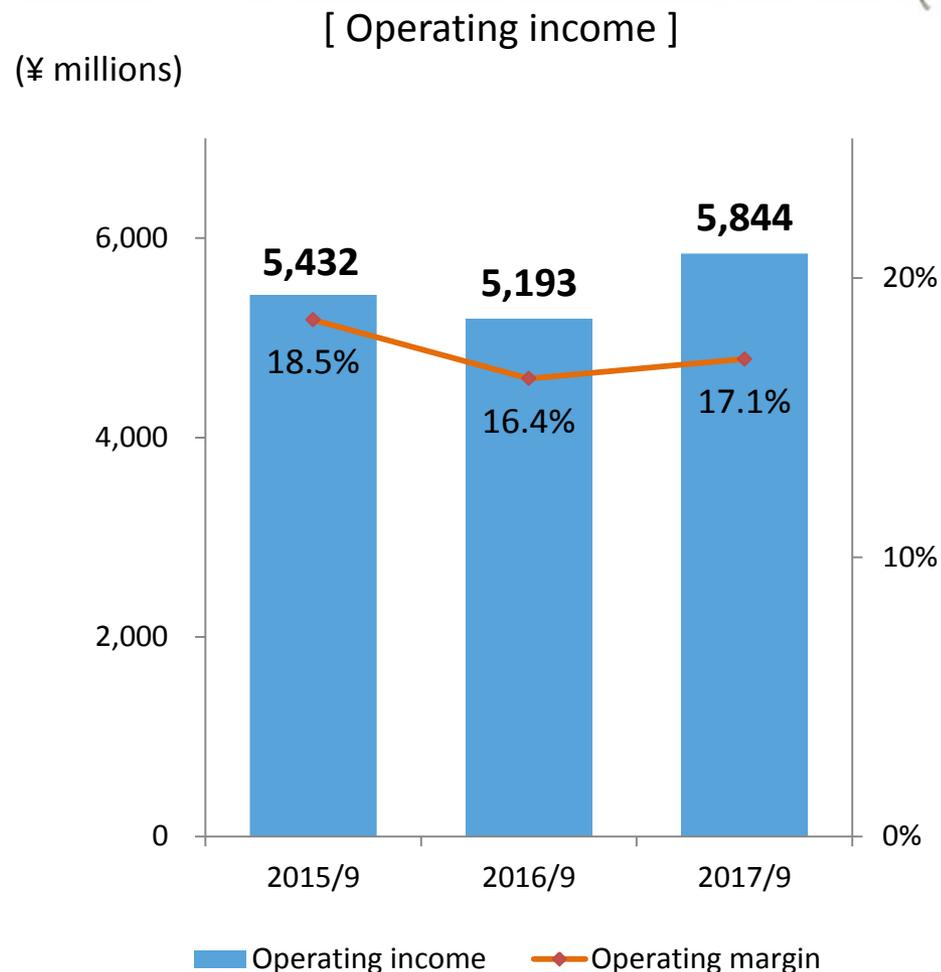
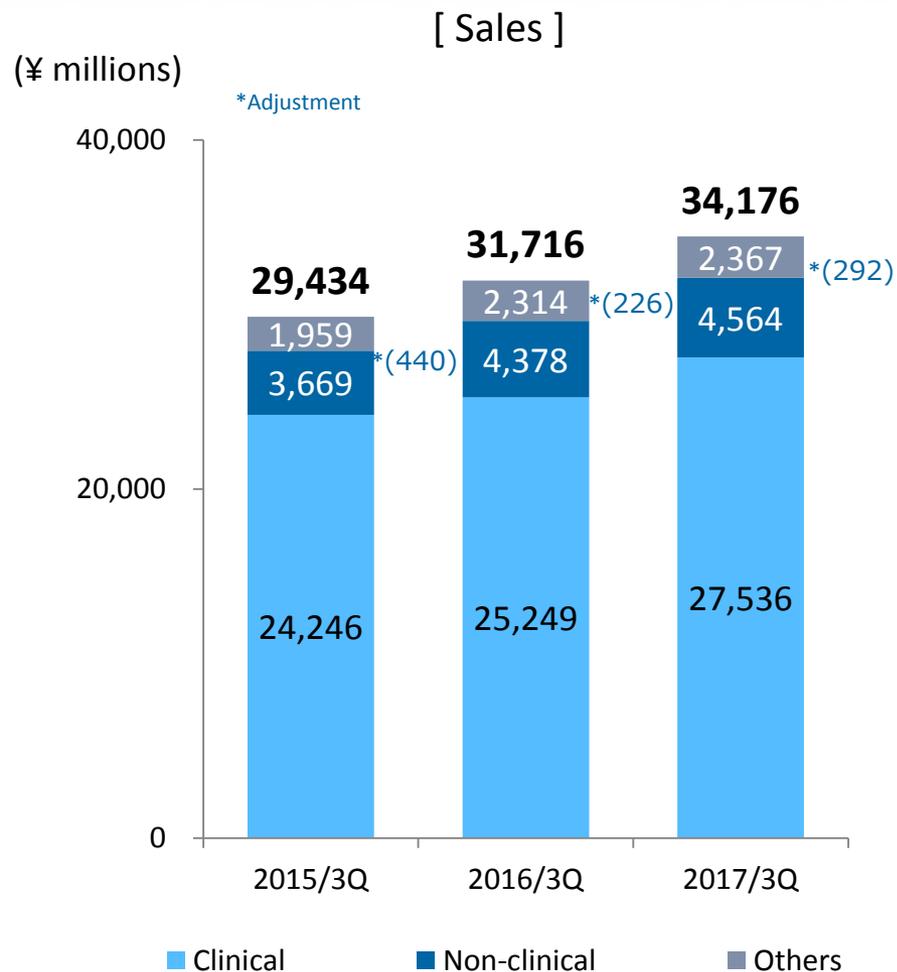
	2016/9		2017/9			
	Orders received (¥ millions)	Backlog (¥ millions)	Orders received (¥ millions)	Percent change (%)	Backlog (¥ millions)	Percent change (%)
CRO Business	34,174	45,586	43,372	26.9	54,935	20.5
CDMO Business	14,179	3,289	14,695	3.6	3,619	10.0
CSO Business	5,824	5,594	4,386	(24.7)	3,095	(44.7)
Healthcare Business	7,415	9,490	7,267	(2.0)	9,129	(3.8)
Total	61,593	63,961	69,722	13.2	70,779	10.7

- Accounts for only the backlog of firm CDMO business orders. There is customer demand for scheduled orders but these are different from firm orders so we have not included these in the backlog.
- Order status is not included for IPM Business because its business conditions are different from those of contract business.

Trend in consolidated Sales & Operating income

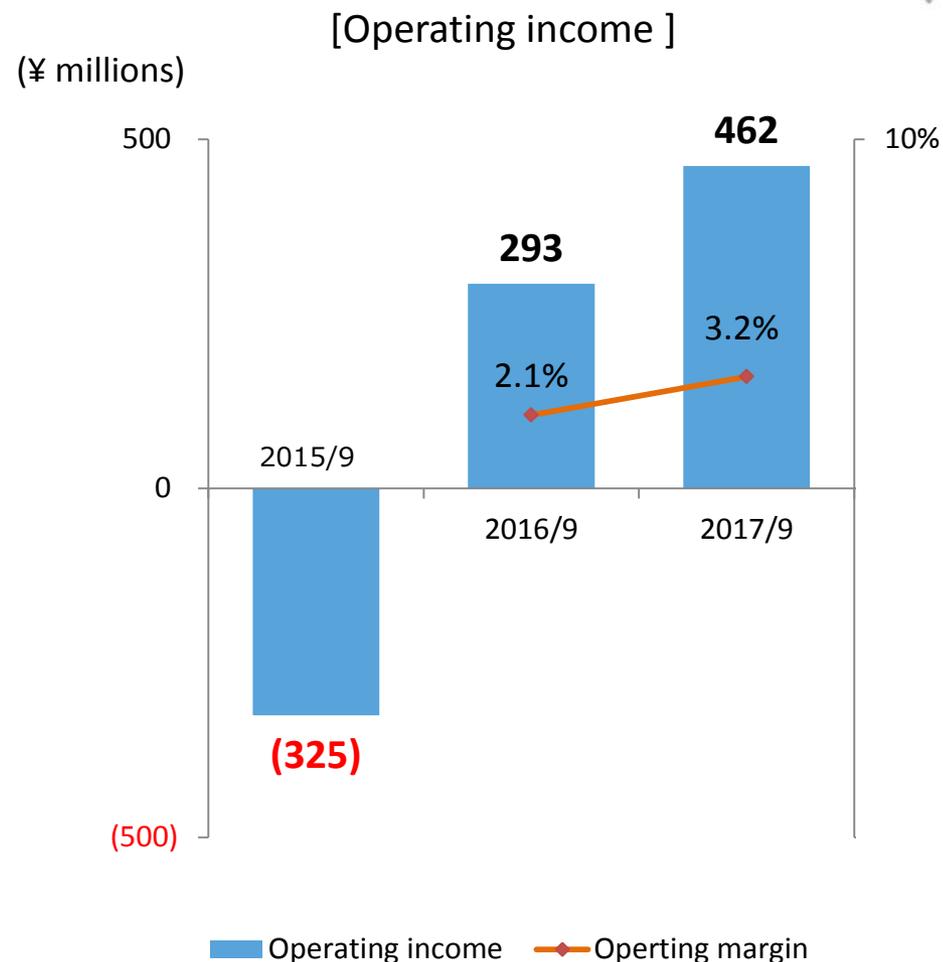
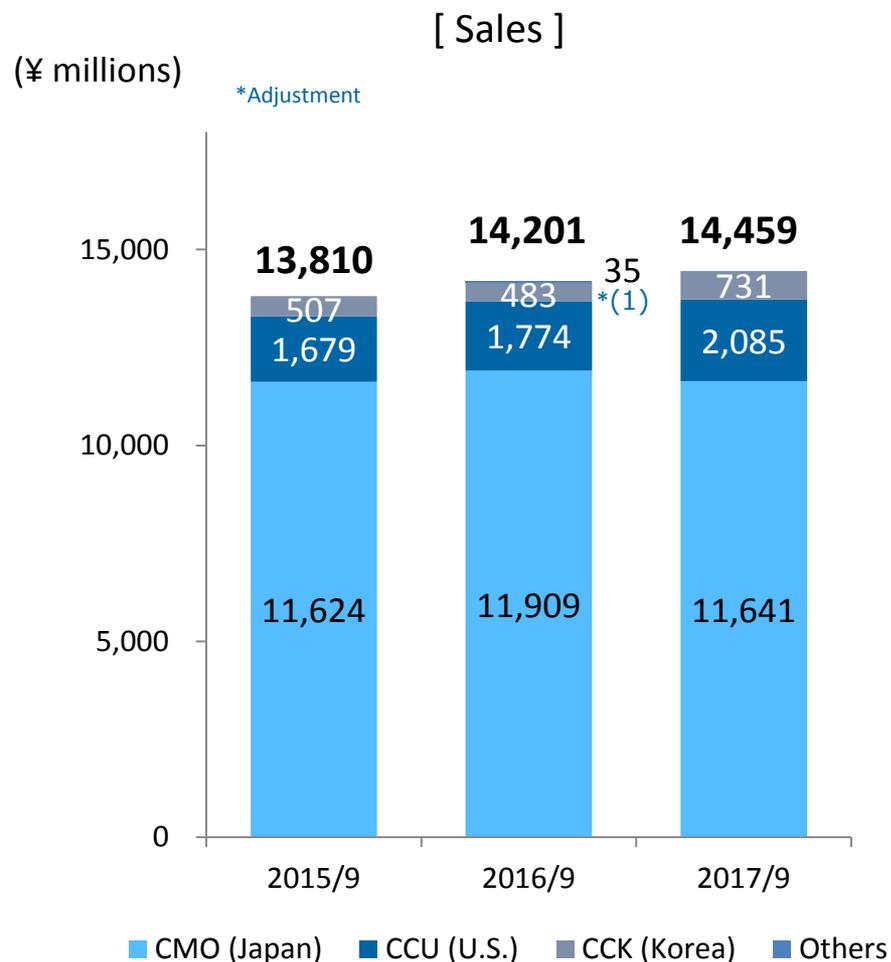


Contract Research Organization (CRO) Business



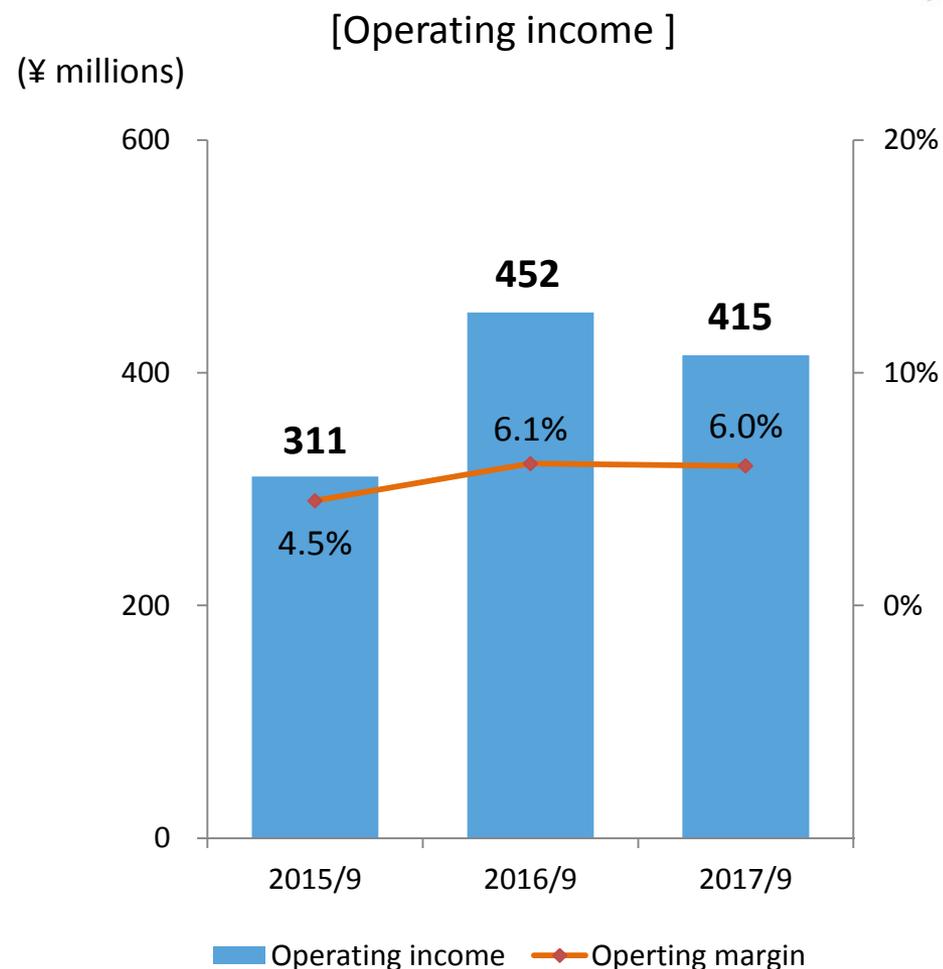
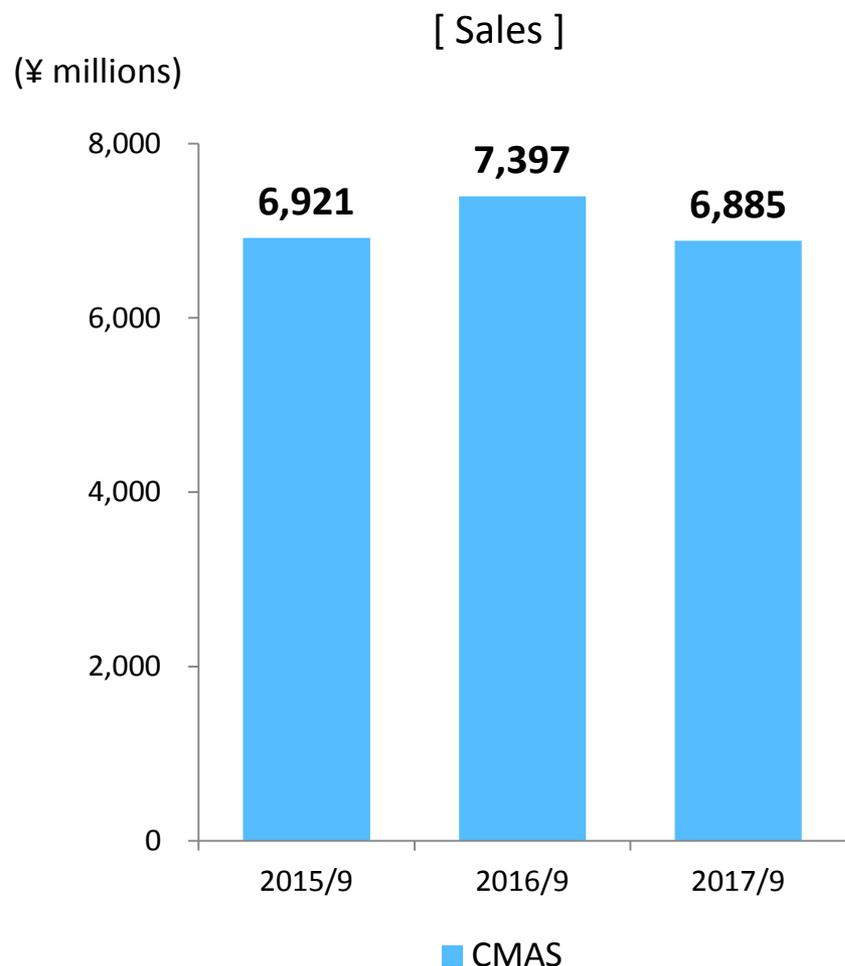
Work to develop human resources with the aim of securing human resources based on robust demand, further expertise, and improving quality. Build a support system related to the field of regenerative medicine. Strengthened Japan-US collaboration in the non-clinical arena especially for companies entering the U.S. market. Established a joint venture with Fosun Pharma group in Suzhou, China that provides support for generic drug filing. Sales and operating income exceeded those of the previous year on growth in new orders and existing contracts.

Contract Development Manufacturing Organization (CDMO) Business



Since we have continued to shift toward the competitive cost structure, low-cost production has progressed and the number of new orders for contract manufacturing of generic drugs has increased as a result. Sales and operating income exceeded those from the previous consolidated fiscal year thanks to robust growth in new and existing contract manufacturing projects.

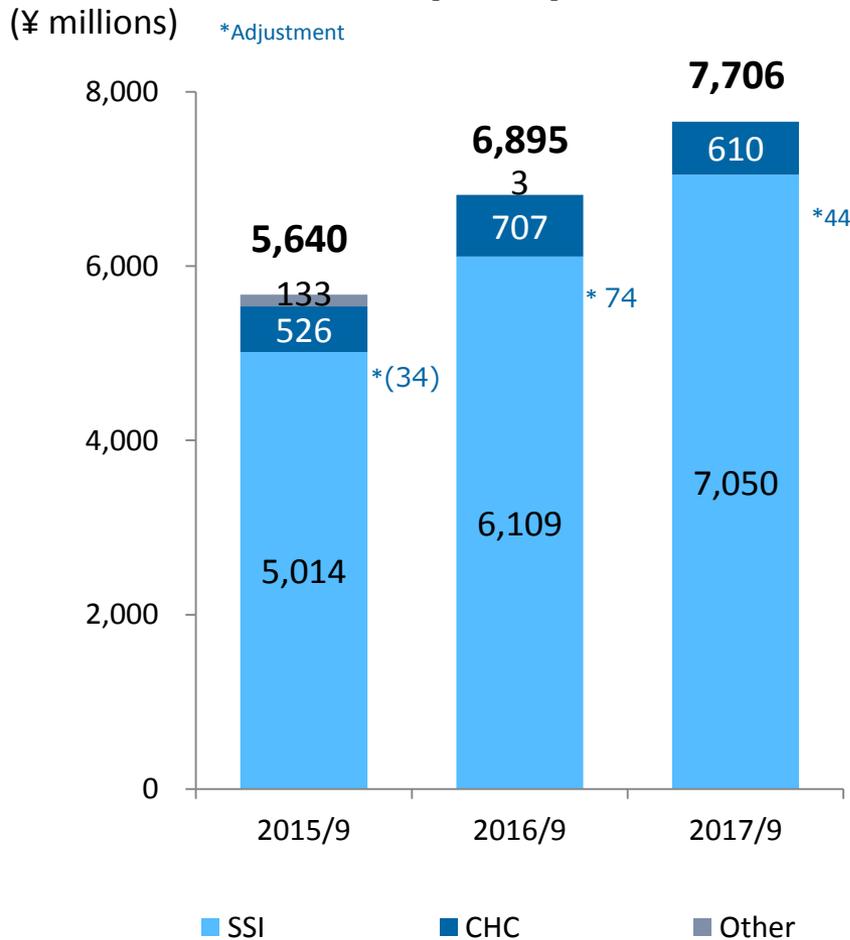
Contract Sales Organization (CSO) Business



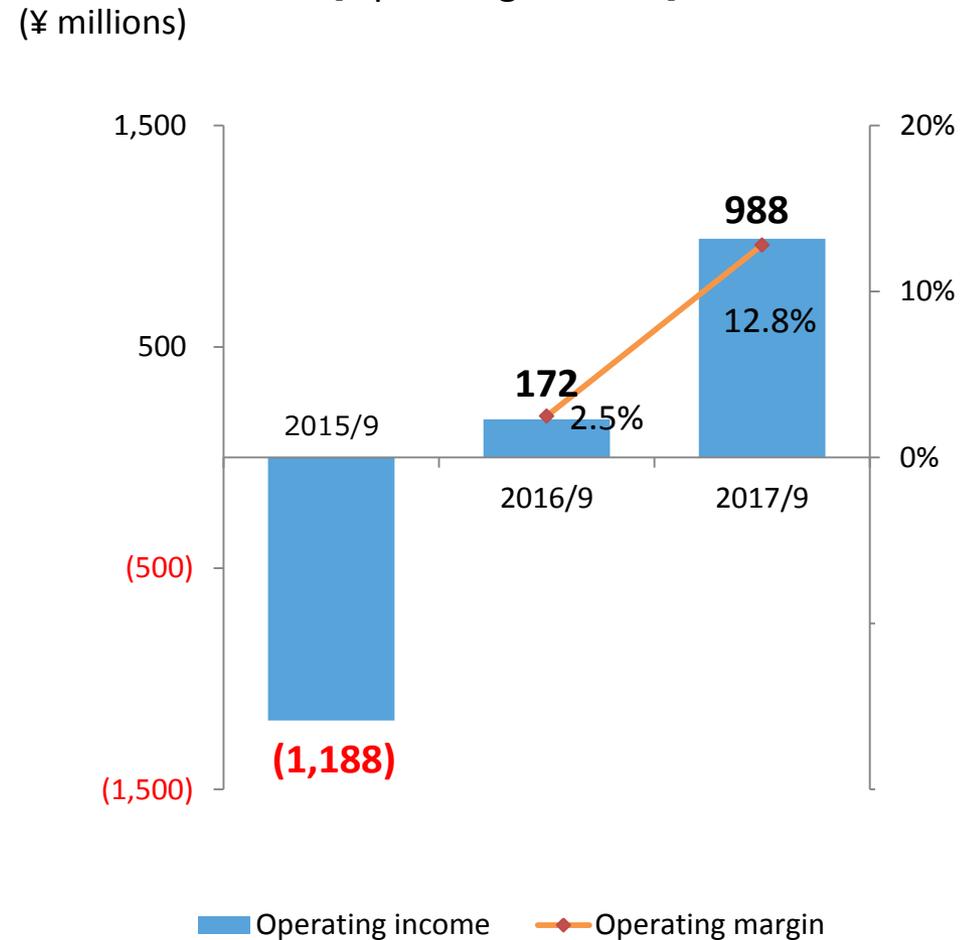
CMIC Ashfield Co., Ltd. has worked steadily to strengthen its capacity to meet demands and move through existing projects. They are also working to expand market share by improving support for client needs, such as by providing multichannel services. Sales and operating profit are below the prior year level due to outsourcing needs of MR dispatch business facing the adjustment stage.

Healthcare Business

[Sales]

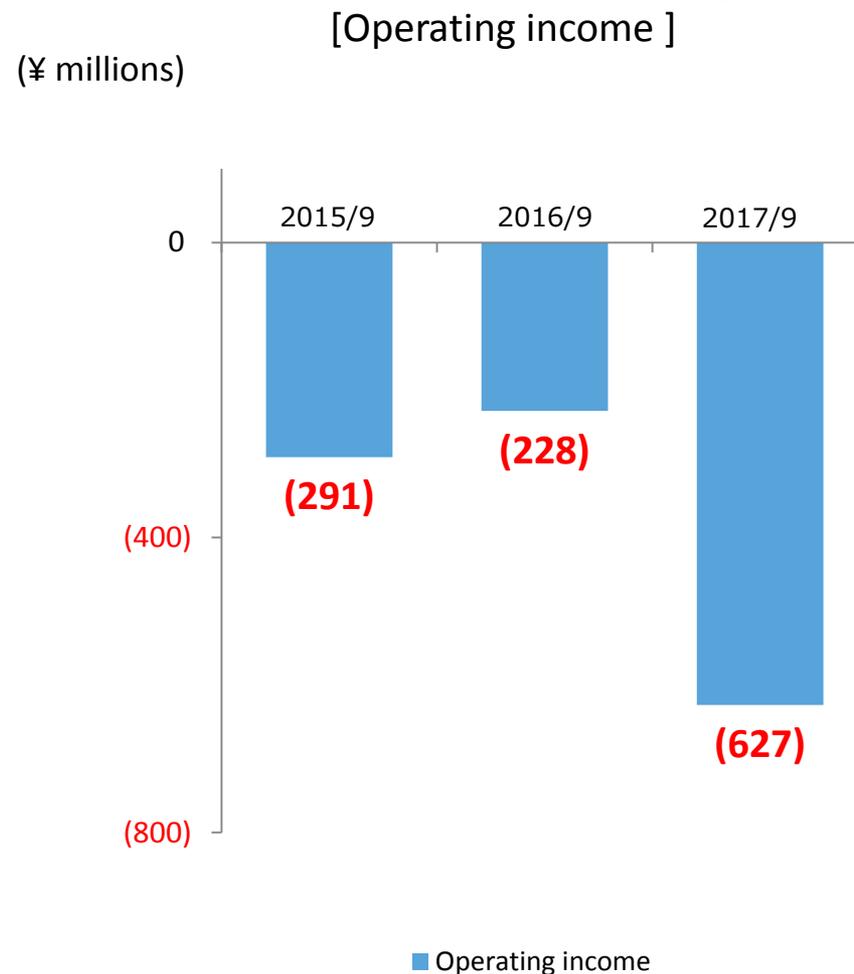
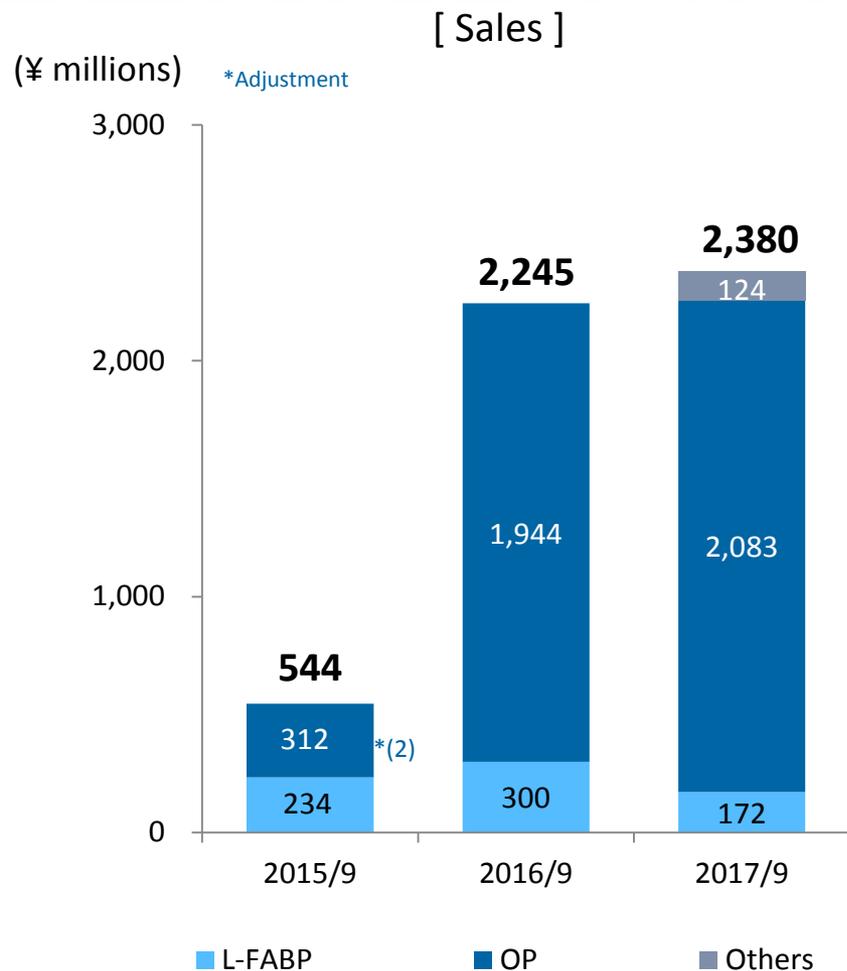


[Operating income]



Promoted the acquisition of new orders through efforts to further strengthen sales and marketing activities in SMO services and expand its medical institute network. Sales significantly exceeded the same period the previous year on robust growth in new orders and existing contracts. Significantly improved profitability and recorded a business profit through ongoing managerial streamlining measures.

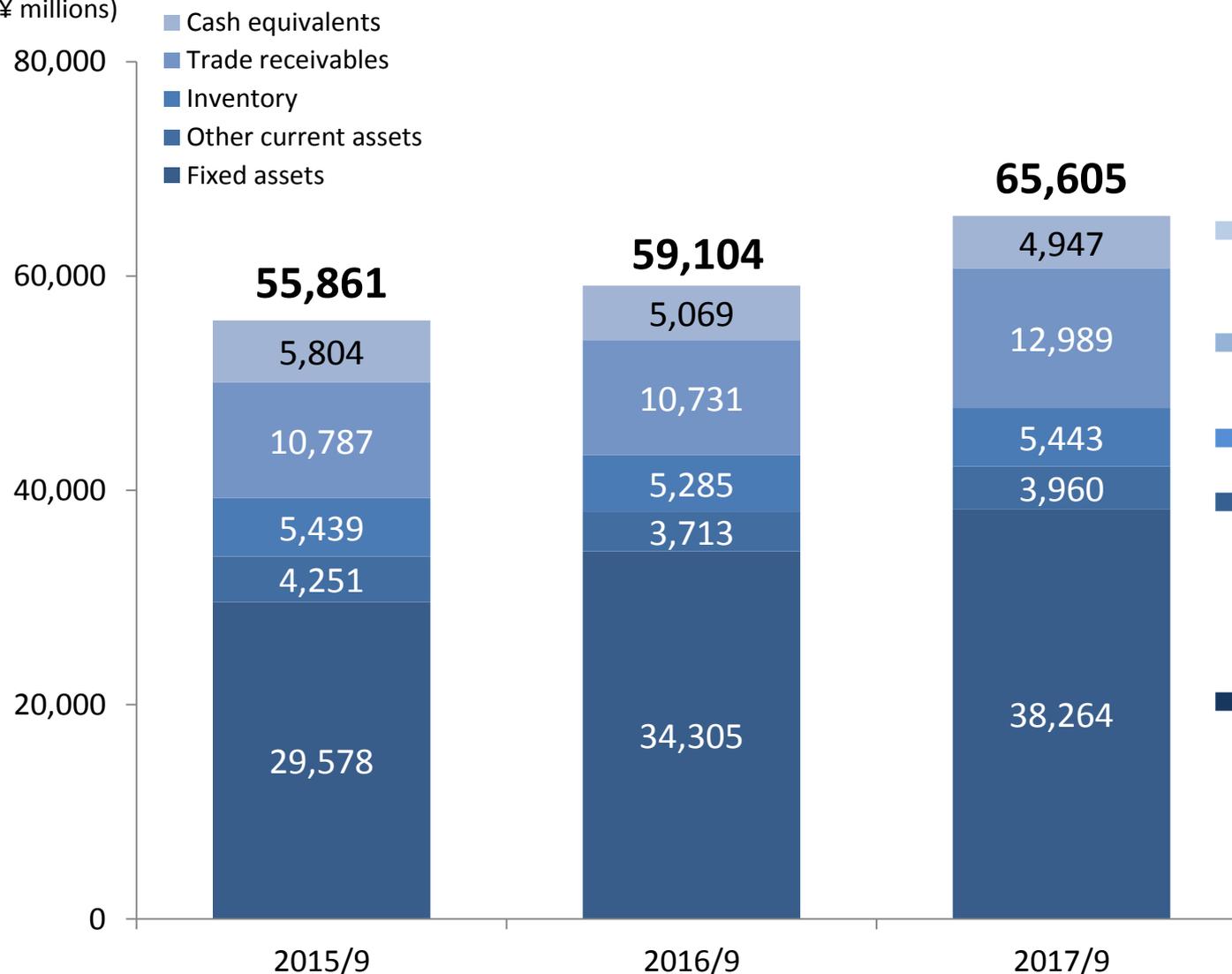
Innovative Pharma Model (IPM) Business



Strengthened the foundation of IPM business by selling orphan drugs including those developed in-house and the drugs that were transferred from pharmaceutical companies. Diagnostics business started selling simple test kits (Dip-test) for the in vitro diagnostic drug. Nation-wide sales of "Zanmira Nail" started as a new solution model. While sales exceeded that of the same period last year, operating profit is lower than that of the same period last year due to sales promotion expenses for "Zanmira Nail" such as advertising and manpower expenses. We are enhancing business development activities toward business scale expansion through provision of new solutions.

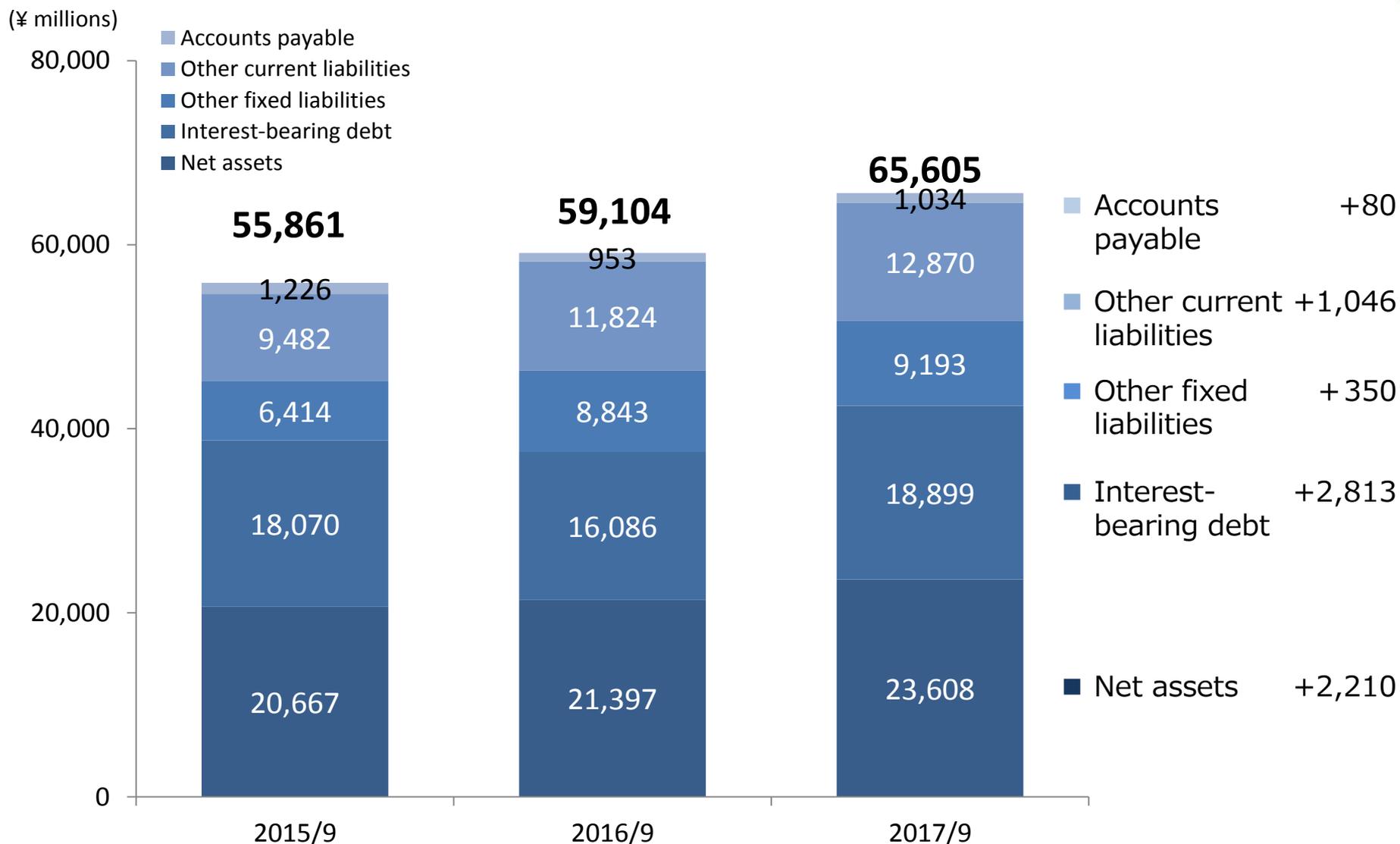
Balance sheet (assets)

(¥ millions)



Total assets	+6,500
Cash equivalents	(121)
Trade receivables	+2,257
Inventory	+158
Other current assets	+247
Fixed assets	+3,959

Balance sheet (liabilities and net assets)



Cash Flows

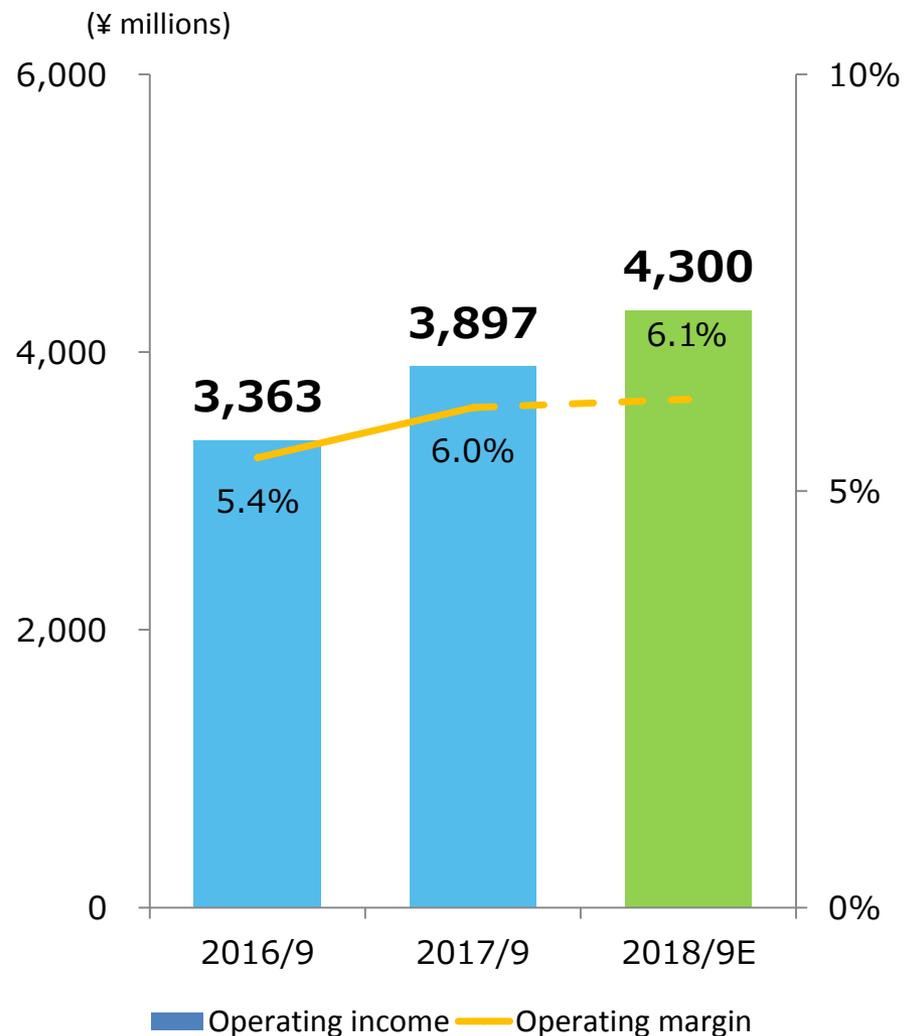
	2016/9	2017/9	(¥ millions) Increase (decrease)	
Cash flows from operating activities	6,493	4,937	(1,555)	[Key factor] (Cash flow from operating activities)
Cash flows from investing activities	(4,639)	(7,541)	(2,901)	<ul style="list-style-type: none"> • Proceeds from profit before income taxes and depreciation • Decline in cash flows from income taxes paid
Cash flows from financing activities	(2,391)	2,458	4,849	(Cash flow from investing activities)
Effect of exchange rate change on cash and cash equivalents	(153)	126	280	<ul style="list-style-type: none"> • Outflow from purchase of property, plant and equipment • Outflow from purchase of investment securities
Net increase(decrease) in cash and cash equivalents	(692)	(19)	673	(Cash flow from financing activities)
Cash and cash equivalents at beginning of period	5,638	4,946	(692)	<ul style="list-style-type: none"> • Inflow from the long-term loans payable • Repayment of long-term loans payable and net decrease in short-term loans-payable
Increase in cash and cash equivalents from newly consolidated subsidiary	—	1	1	
Cash and cash equivalents at end of period	4,946	4,928	(17)	



Forecast for FY ending Sept. 2018

Forecast for FY ending Sept. 2018

	2017/9 Actual	2018/9 Forecast	Change (%)
	(¥ millions)	(¥ millions)	
Sales	65,282	70,500	8.0
Operating income	3,897	4,300	10.3
Ordinary income	3,732	3,930	5.3
Profit attributable to owners of parent	1,550	1,700	9.6
Earnings per share	¥82.90	¥90.89	



Forecast for FY ending Sept. 2018 (by segment)

		2017/9 results (¥ millions)	2018/9 forecast (¥ millions)	Change (¥ millions)	Change (%)
CRO business	Sales	34,176	36,500	2,323	6.8
	Operating income	5,844	5,950	105	1.8
CDMO business	Sales	14,459	15,900	1,440	10.0
	Operating income	462	480	17	3.9
CSO business	Sales	6,885	7,300	414	6.0
	Operating income	415	450	34	8.4
Healthcare business	Sales	7,706	7,800	93	1.2
	Operating income	988	1,050	61	6.2
IPM business	Sales	2,380	3,400	1,019	42.8
	Operating income	(627)	(450)	177	—
Adjustments	Sales	(326)	(400)	(73)	—
	Operating income	(3,186)	(3,180)	6	—
Consolidated	Sales	65,282	70,500	5,217	8.0
	Operating income	3,897	4,300	402	10.3

CRO business activities for FY2018

- ▶ Improved expertise to meet the need for increasingly sophisticated products development (e.g. anticancer drugs, regenerative medicine products, medical devices)
- ▶ Global support through outbound enhancement
- ▶ Enhanced clinical research and post-marketing support business based on database
- ▶ Seamless collaboration between Japan and the United States for non-clinical operations, started a business to support generic drug filing in China, expanded regenerative medicine-related operations

2018/9E
(¥ millions)

Sales	36,500
Operating income	5,950



CMIC, INC. US Lab



CPT China
(support for generic drug filing)



Bioresearch Center
(Yamanashi Prefecture)

CDMO business activities for FY2018

- ▶ Low-cost production through productivity and efficiency improvements
- ▶ Enhanced formulation development skills by acquiring new technologies
- ▶ Production system established at the new injection building

2018/9E
(¥ millions)

Sales	15,900
Operating income	480



Shizuoka Plant

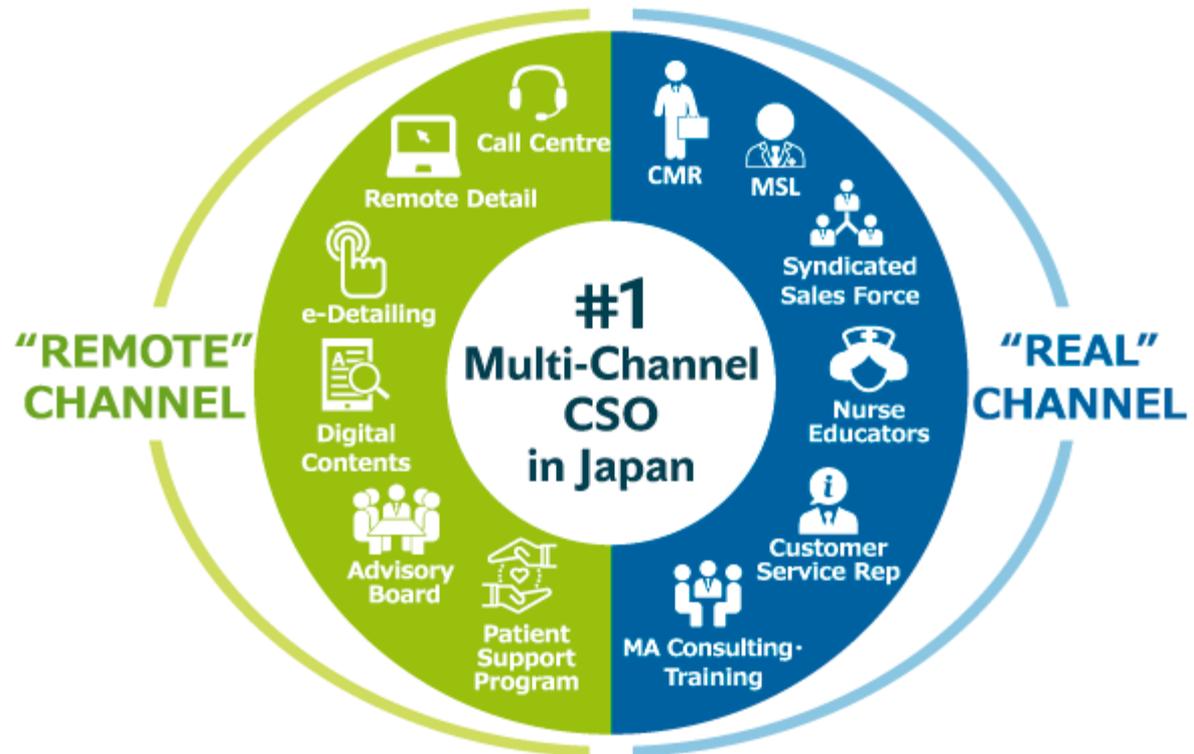


New injection building (Ashikaga)

CSO business activities for FY2018

- ▶ Multi-channel solution enhancement and market share expansion
- ▶ Comprehensive commercial solution proposal through combination of services (e.g. conventional C-MR, syndicated MR, MSL, Call center, remote)

	2018/9E (¥ millions)
Sales	7,300
Operating income	450

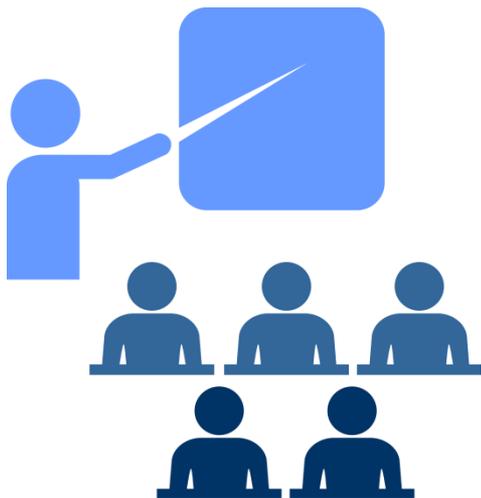


Healthcare business activities for FY2018

- ▶ Maintaining strong focus on quality and compliance
- ▶ Contribution to the improvement of healthcare productivity
- ▶ Providing new services such as Medical Concierge Services
- ▶ Establishment of digital health business towards "Patient-centered care"

2018/9E
(¥ millions)

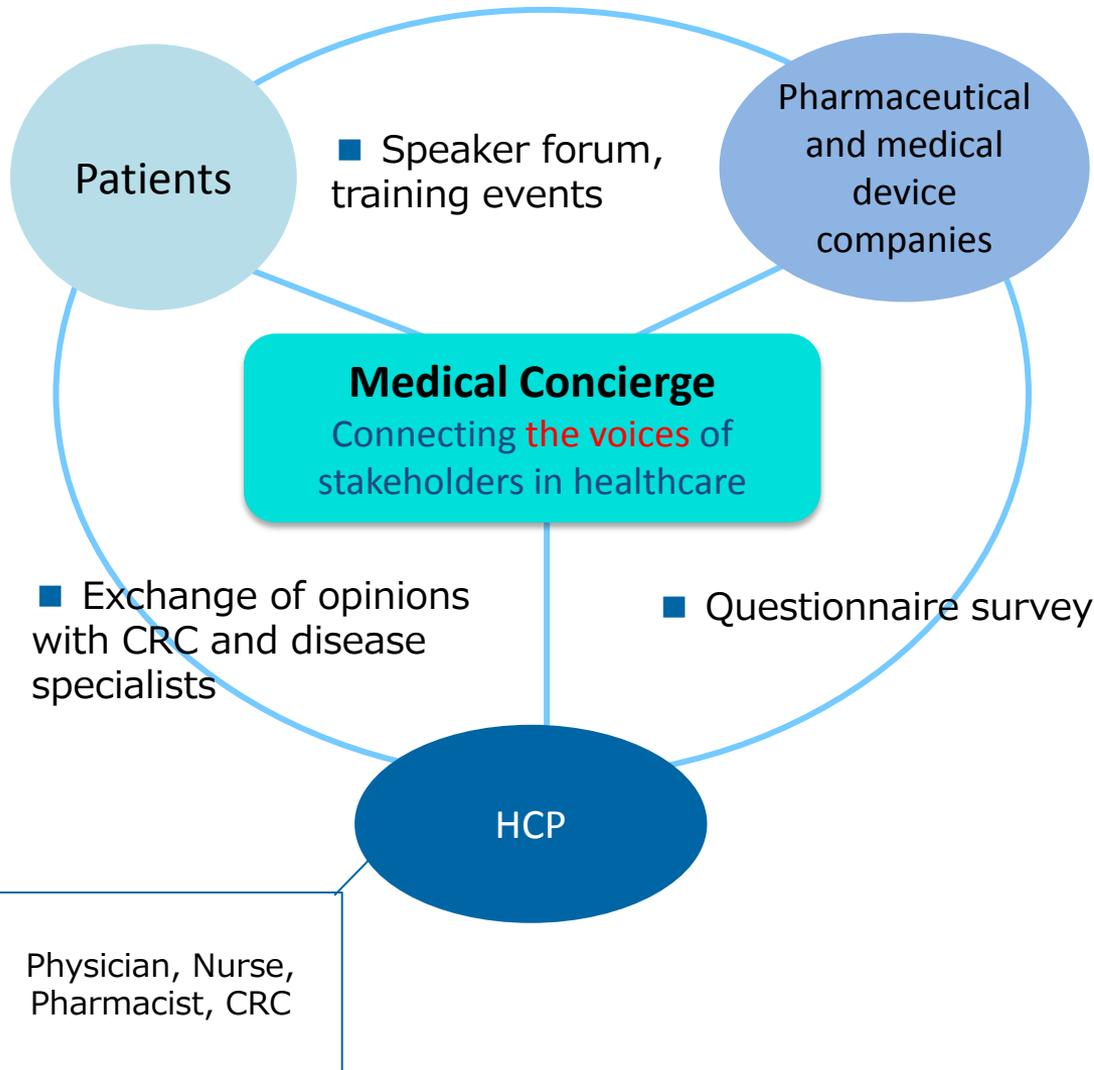
Sales	7,800
Operating income	1,050



Expert lectures on clinical research ethics (basic)
(1 class : 3 hours x 12 lectures)
<Lecturer>
Professor Shoichi Maeda , Keio University
Specialty: Medical jurisprudence, Medical ethics,
Medical quality and safety science



Healthcare business – Medical Concierge –



Commissioned projects

[Questionnaire survey]

- ▶ Survey on heart failure studies
- ▶ Survey on orthopedic medical instruments
- ▶ Survey on Dermatology area
- ▶ Survey on formulation development

[Interview]

- ▶ CRC interview on medical device A
- ▶ CRC interview on medical device B
- ▶ CRC interview on medical device C

[Workshop/Speaker Forum]

- ▶ Speaker request for Speaker Forum
- ▶ Lecturer for CRA training session

[Other]

- ▶ Interview request to physicians

IPM business activities for FY2018

- ▶ Provision of orphan drugs that utilize the functions of CMIC Group and MEDIPAL Group in an innovative manner
- ▶ Portfolio expansion (additional indications/formulation changes) of existing products
- ▶ Contributions to the stable supply of essential drugs, introduction of new orphan drugs, and providing support to foreign companies entering the Japanese market
- ▶ Expanding market opportunities for Kidney disease biomarker (L-FABP)

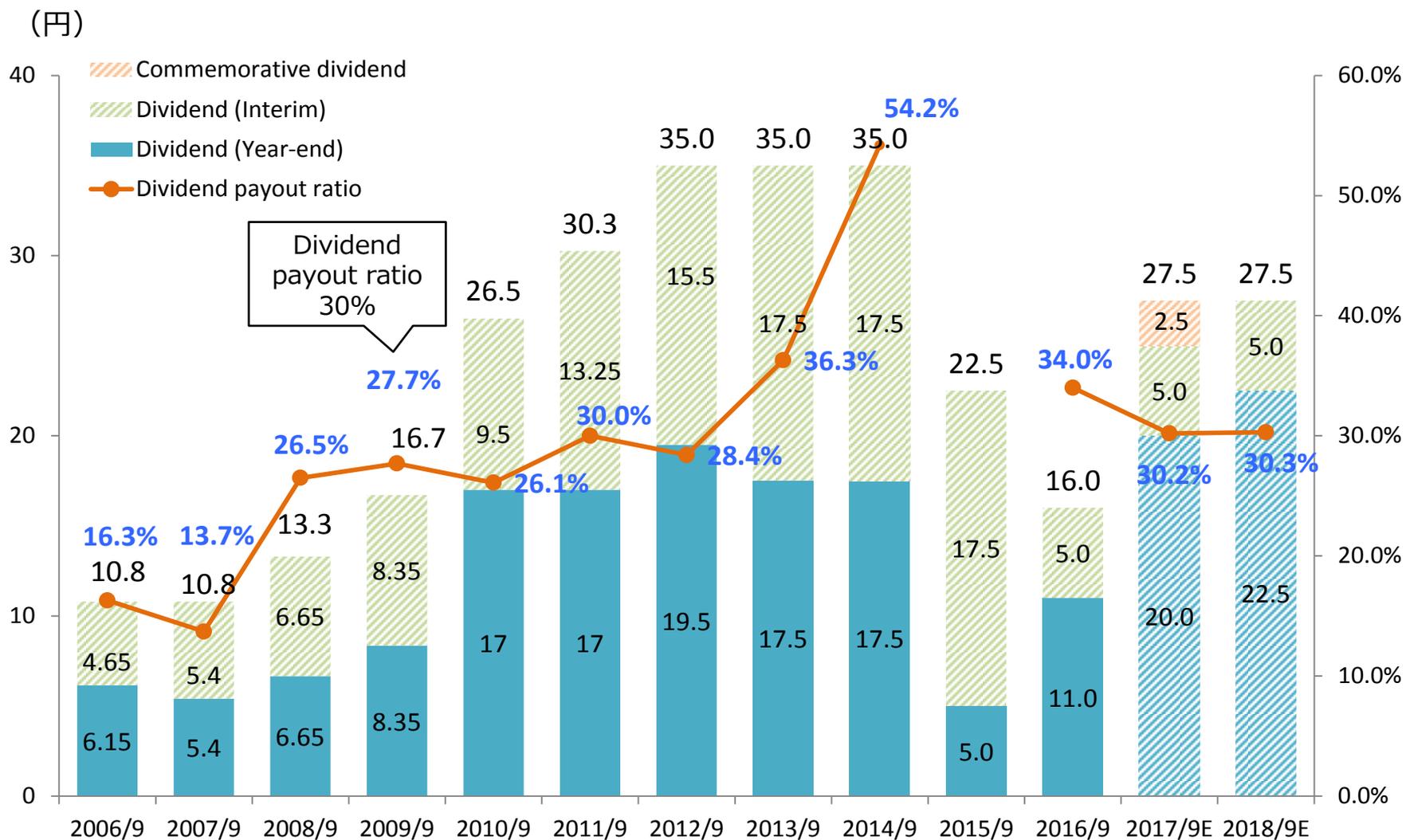
2018/9E

(¥ millions)

Sales	3,400
Operating income	(450)



Dividends per share and trend of ordinary dividend payout ratio





Progress of Project Phoenix

CMIC HOLDINGS Co., Ltd.

**Kazuo Nakamura,
Chairman & CEO**

CMIC Overview



CMIC's unique business model (PVC)

CSO business

(Contract Sales Organization)

Sales and marketing support

Healthcare business

(Healthcare)

Business that enhances individual health value

Pharmaceutical Value Creator

Strategic partner for pharmaceutical companies

CDMO business

(Contract Development Manufacturing Organization)

Formulation development and manufacturing support

IPM business

(Innovative Pharma Model)

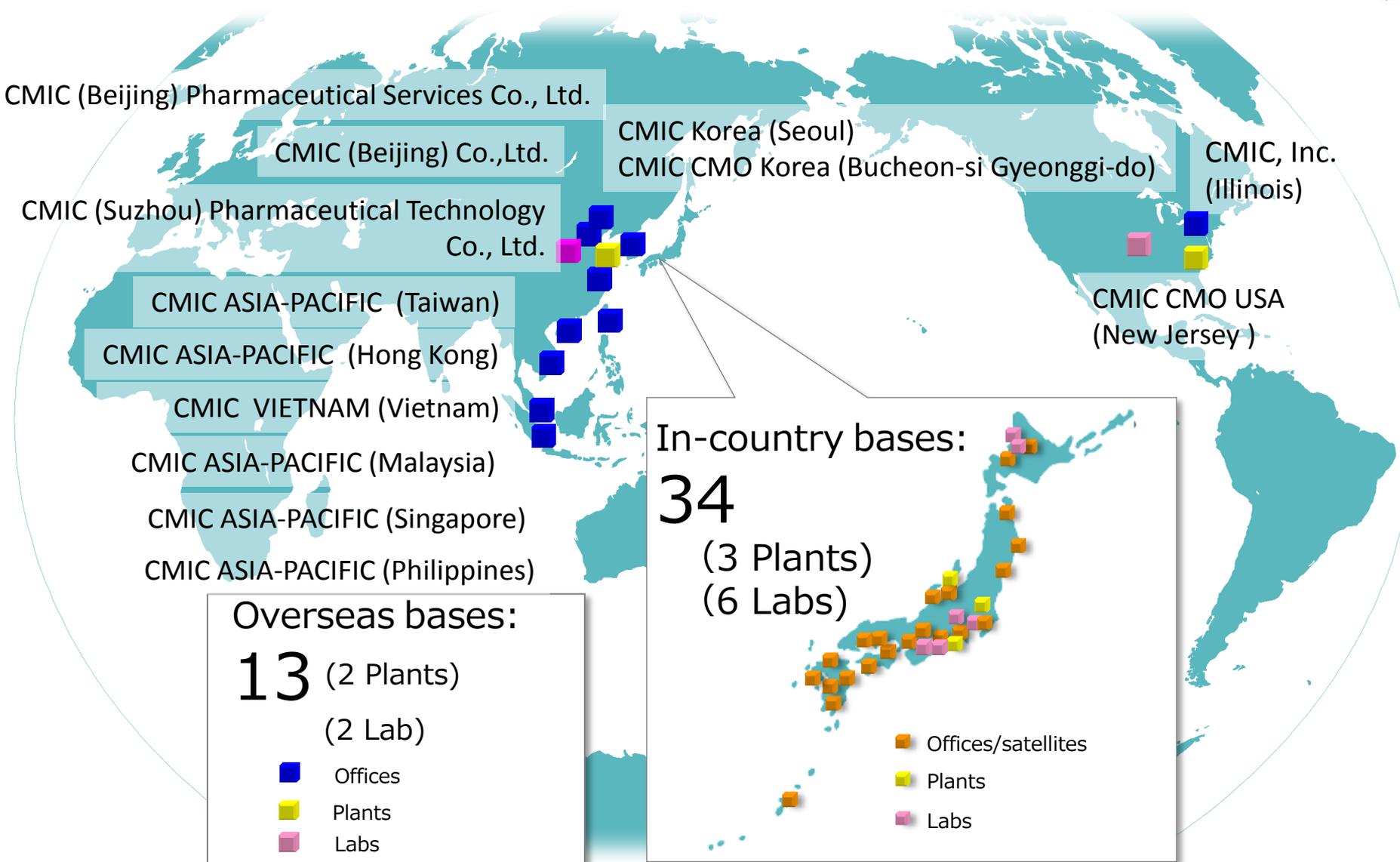
Pharmaceutical company that exists for the benefit of pharmaceutical companies

CRO business

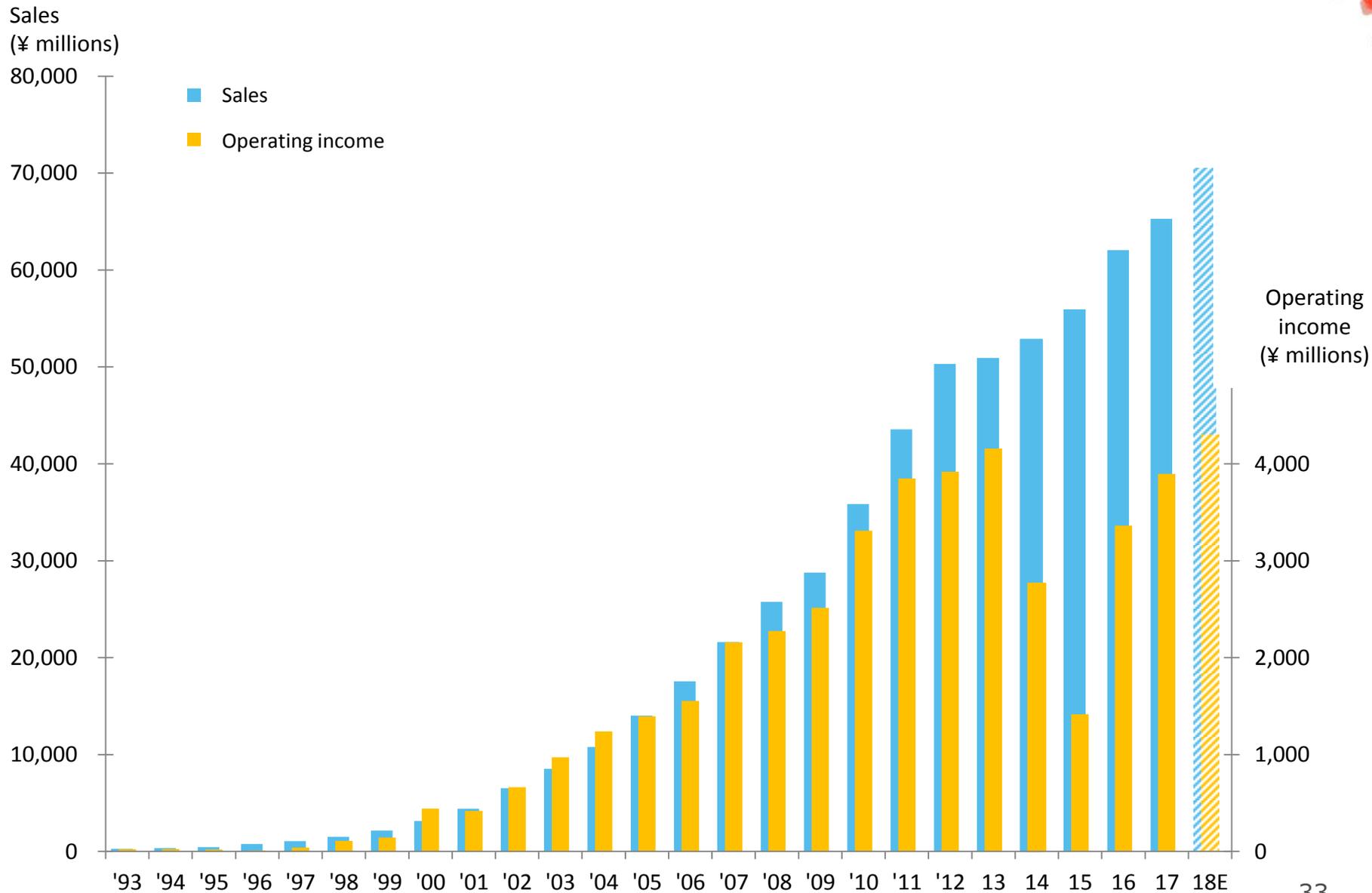
(Contract Research Organization)

Drug development support

CMIC Group Global Coverage



Sales and Operating Income Trend

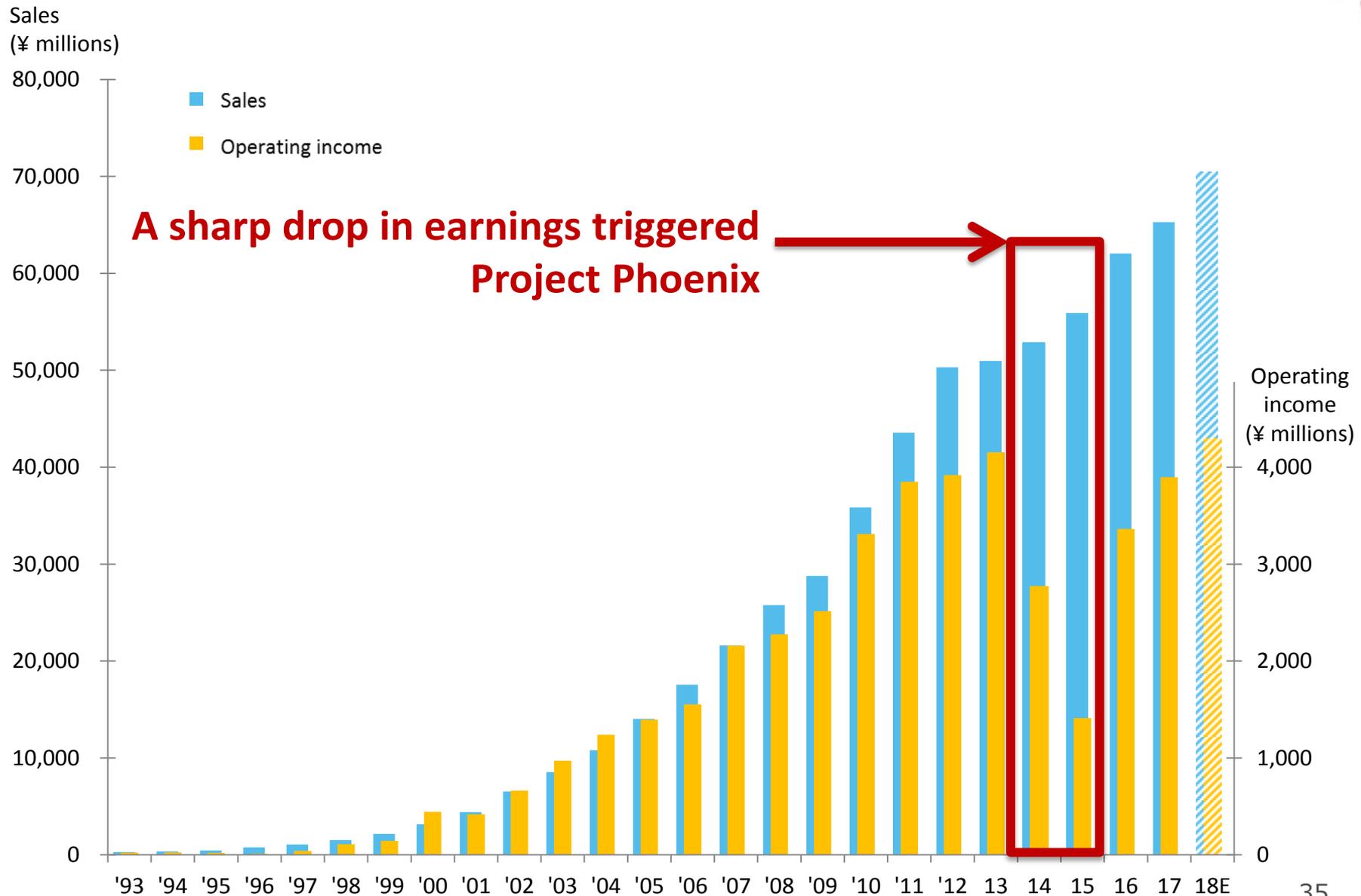




Project Phoenix

**Started in October 2014
to “achieve profit driven growth”**

Sales and Operating Income Trend



Project Phoenix



Project Phoenix started in October 2014 to achieve profit driven growth

Phoenix 1.0 (October 2014—March 2016)

- ▶ Establishment of corporate culture (CMIC'S CREED)
- ▶ Positive turnaround of unprofitable business

Phoenix 2.0 (April 2016—March 2018)

- ▶ Reorganization and personnel training for agile management
- ▶ Providing solutions using PVC functions
- ▶ Started providing Innovative Pharma Model platform

Phoenix 3.0 (Scheduled to start in April 2018)

Project Phoenix 1.0 (October 2014—March 2016)

“Project Phoenix 1.0 ” started in October 2014

To eliminate departmental silos and maintain high motivation for all employees



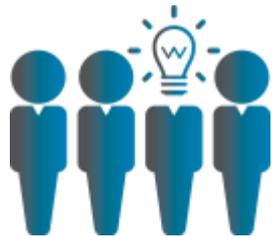
[Establishment of corporate culture]

- ▶ CMIC'S CREED



[Positive turnaround of unprofitable business]

- ▶ CDMO business
- ▶ SMO business



[Other initiatives]

- ▶ Work style reform
(Relocation of the head office: Non-territorial workplace, Mobile work environment)
- ▶ Enhancement of human resources (Establishment of training center)

Further penetration of “CMIC’S CREED”

Our CREED

We are determined to bring innovation to healthcare so that all people, regardless of age and gender, can live their precious lives according to their will. This is our aspiration as the CMIC Group.

Whether in childhood, when brilliance has yet to blossom, or in late adulthood, when potential has bloomed, we respect every individual’s drive to live fully in the moment. We shall sincerely address each and every life. We shall overlook no one.

To achieve this, we shall continually challenge ourselves to strive for a better future. We shall transform ourselves, seek new vantage points, turn our unwavering passion into values, and continue to contribute to individuals and society.

With unchanging determination at heart, we change



CREED Workshop





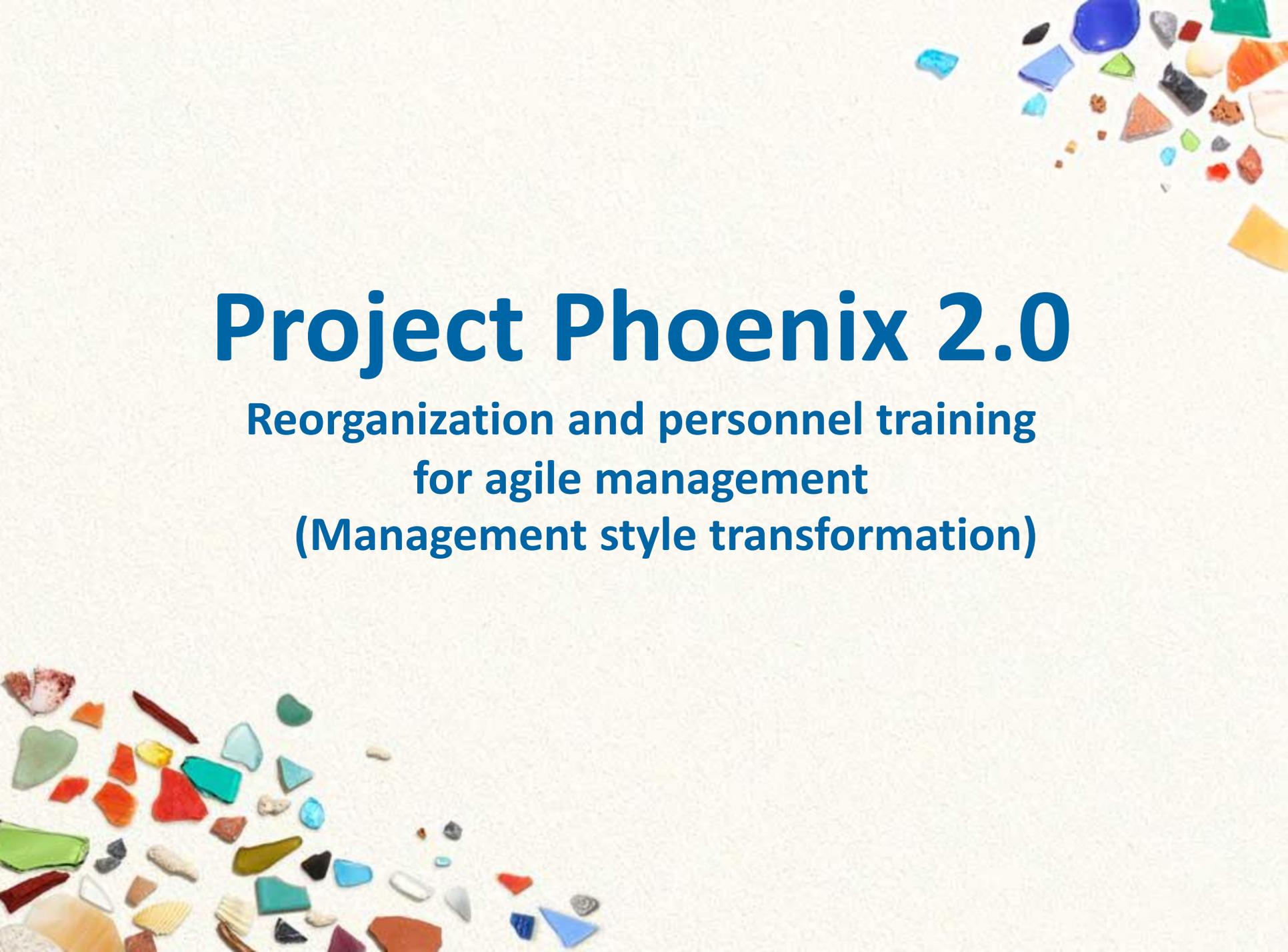
Project Phoenix 2.0

(April 2016-March 2018)

“Project Phoenix 2.0” has been on-going since April 2016

- ▶ Reorganization and personnel training for agile management (Management style transformation)
- ▶ Providing solutions using PVC functions
- ▶ Started providing Innovative Pharma Model platform





Project Phoenix 2.0

Reorganization and personnel training
for agile management
(Management style transformation)

For agile management (speedy management to address changes in business environment)

Established an agile decision making team in addition to the reporting lines in the organizational chart

“Nakamura-Juku (Institute)”
for executive trainees



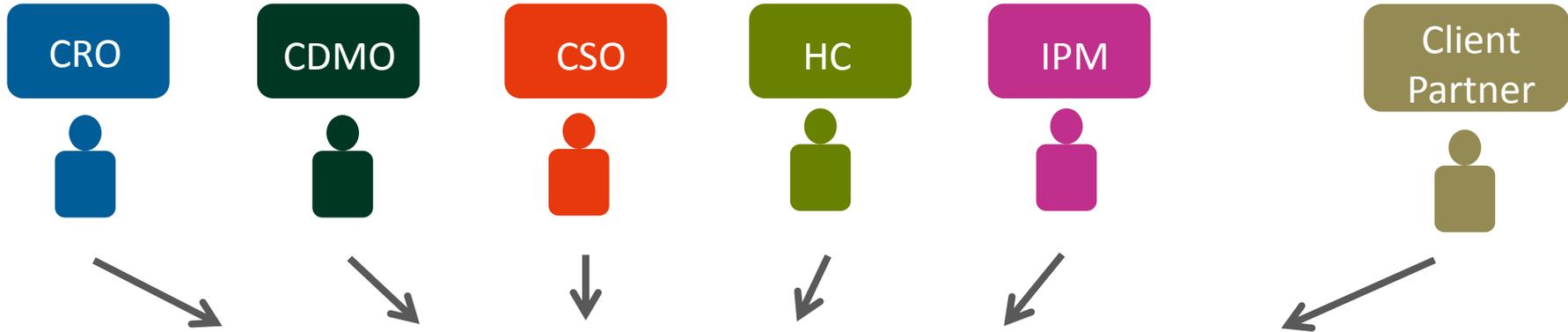
Mid- to long-term
strategy development
team “Hayabusa”

(means Falcon in Japanese,
symbol of speed and agility)

Kicked off in June 2017

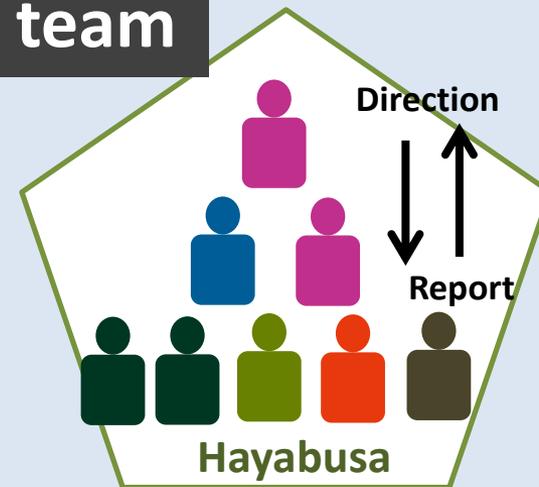
Founded in 2003

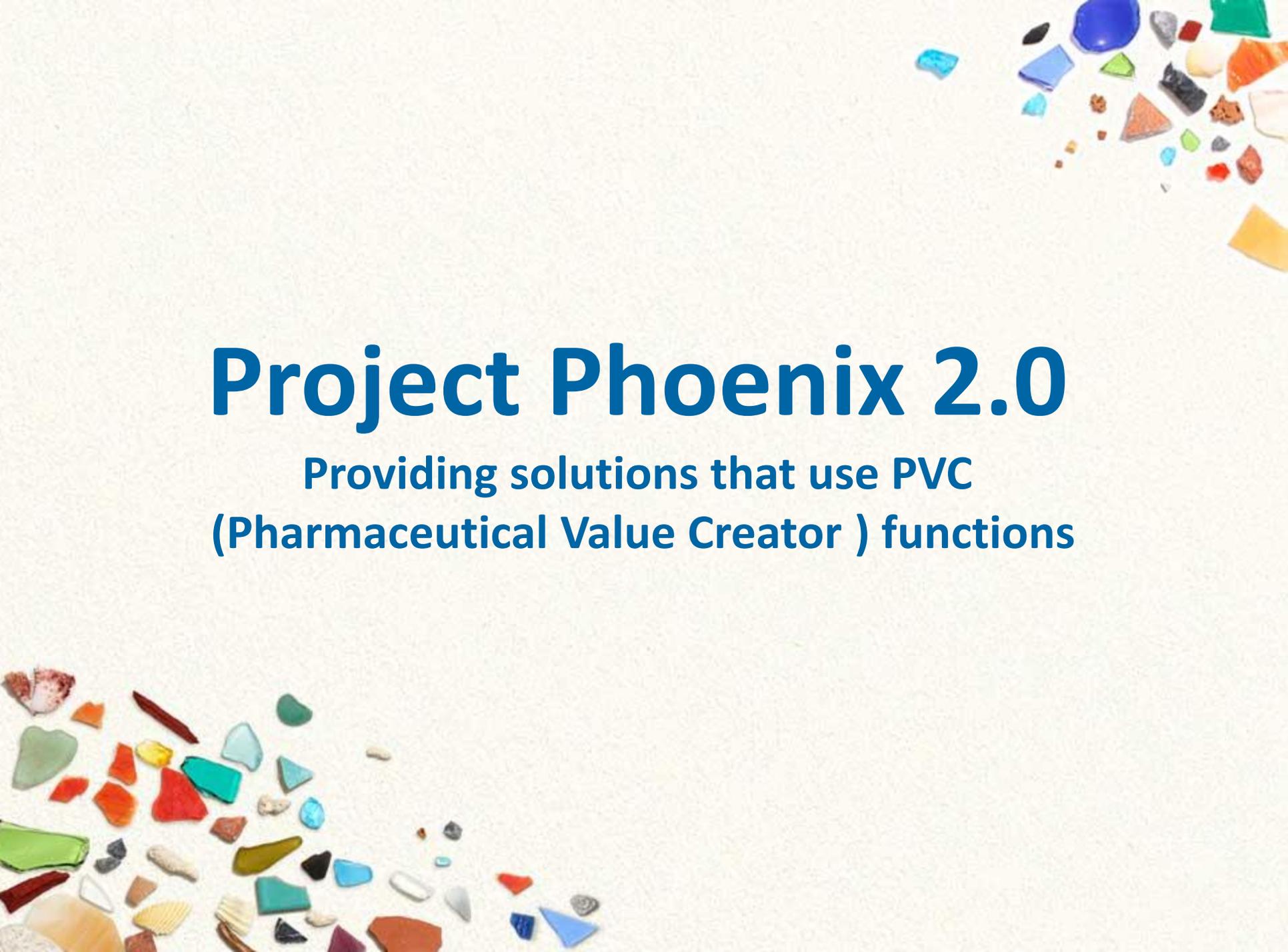
Management style transformation (Team "Hayabusa")



Quick formation of management team

Established an agile decision making team in addition to the reporting lines in the organizational chart



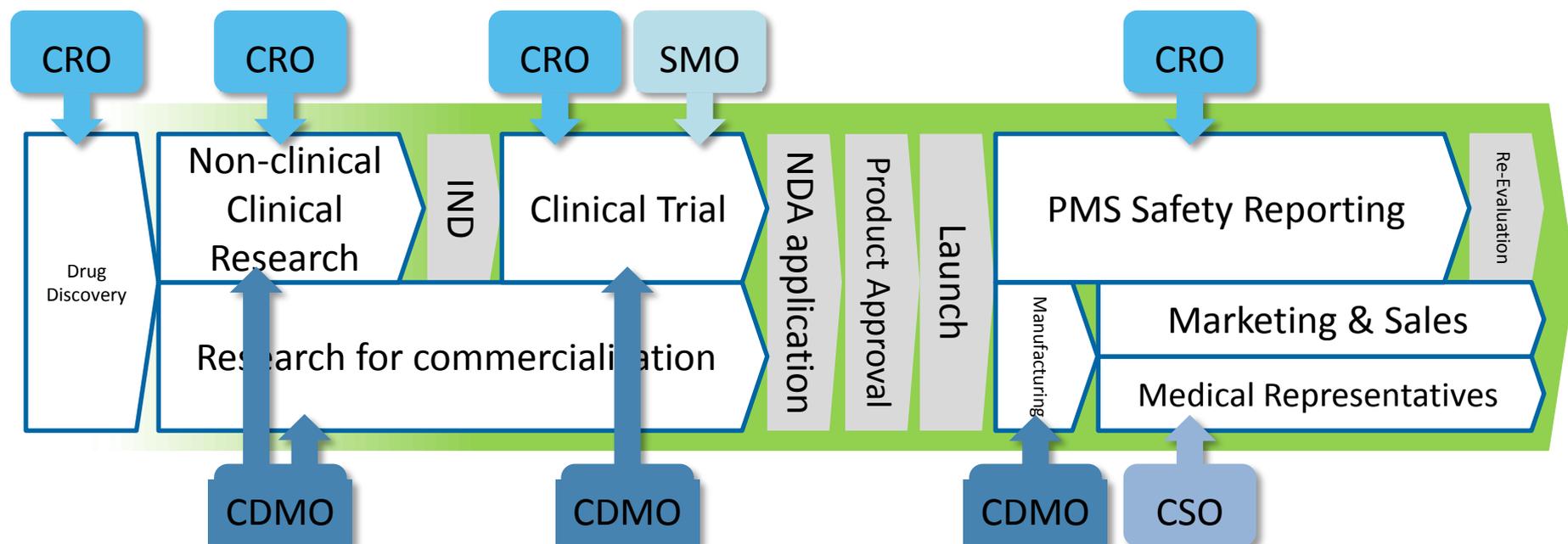


Project Phoenix 2.0

Providing solutions that use PVC
(Pharmaceutical Value Creator) functions

What is PVC?

Comprehensively support the value chains of pharmaceutical companies for the sake of patients who need medicines



Business Solutions

Japan Business Solution

- ◆ Support those companies with no foothold in Japan to enter the 2nd biggest market in the world

Biologics Business Solution

- ◆ Comprehensive support for biologics development

Oncology Business Solution

- ◆ Comprehensive support for the field of oncology to meet the unique needs of this highly-specialized therapeutic area

Generic Drug Business Solution

- ◆ Comprehensive support for development and manufacturing of generics optimizing quality-cost trade-off

Academia Business Solution

- ◆ Comprehensive support for development of innovative academic seeds

Orphan Drug Business Solution

- ◆ Stable supply of medicines to orphan diseases patients

Herbal Medicine Business Solution

- ◆ Stable supply & market expansion of herbal medicines produced in Japan

Examples of PVC solutions

Examples of PVC solutions for the companies newly entering the Japanese market

Company	Products	Support by CMIC Group
A	Metabolic disease	<ul style="list-style-type: none"> ➤ CRO: RA, CTD development, Drug price consulting, P3 monitoring, PV ➤ CDMO: IMP, secondary packaging ➤ Healthcare: Call center ➤ CSO: MR dispatch (10 reps) ➤ PMS: PMS operations
B	Biosimilar	<ul style="list-style-type: none"> ➤ CRO: RA, PV ➤ CSO: 10 MR
C	Central nervous system	<ul style="list-style-type: none"> ➤ CRO (Non-clinical): Non-clinical test ➤ CDMO: IMP, acceptance test, commercial packaging, release ➤ CSO : MR dispatch ➤ PMS
D	Central nervous system	<ul style="list-style-type: none"> ➤ Supported the start-up of Japanese affiliate ➤ Full-outsourcing of product development is planned for CMIC Group ➤ CRO: RA consulting started

Examples of PVC solutions

Support of entering the pharmaceutical industry from a different sector

Company	Products	Support by CMIC Group
E	Long-listed products and others	<ul style="list-style-type: none"> ➤ Full-support : New drug business unit start-up, Business development consulting, RA, PV, Manufacturing technology transfer, Manufacturing, and Distribution

Case of domestic companies fully outsourcing the new product development to CMIC group

Company	Products	Support by CMIC Group
F	Dermatological condition	<ul style="list-style-type: none"> ➤ CRO: P3 study ➤ SSI: P3 study ➤ CDMO: Formulation development, IMP manufacturing, Commercial production ➤ CSO: MR dispatch
G	Area of metabolic disease, cardiovascular, and others	<p>Following orders to be received</p> <ul style="list-style-type: none"> ➤ CRO (Non-clinical): Analysis ➤ CDMO : Formulation development, IMP manufacturing ➤ CRO: Development support from regulatory strategy to POC ➤ Business Development: License-out support



Project Phoenix 2.0

Starting providing Innovative Pharma Model (IPM) platform

IPM Business Objectives

IPM platform for pharmaceutical companies and patients

Utilization of Marketing Authorization

- Utilization of various licenses held by the CMIC Group
- Executing the functions of pharmaceutical companies on their behalf



License holding

- Holding marketing authorization is not the ultimate objective
- MA transfer may be an option if somebody is interested
- Provision of various business strategy options to pharmaceutical companies



Products needed by patients

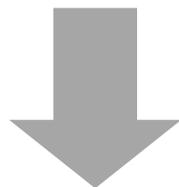
- Low performing products of pharmaceutical companies
- Launching academia and Bio-venture drug seeds



IPM Platform

(Domestic pharmaceutical companies)

Domestic pharmaceutical companies



Low performing products of pharmaceutical companies



CMIC

Pharmaceutical Value Creator

Marketing Approval Holder (MAH)

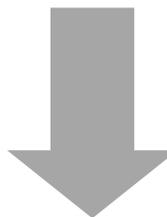
Using all functions that are possessed by the CMIC Group including development, manufacturing, and sales

MA Transfer/
Notification



MHLW

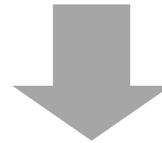
Supply



Medical institutions/
Patients

IPM Platform (Foreign pharmaceutical companies that have no foothold in Japan)

Foreign pharmaceutical companies, academia, and Bio-venture that have no foothold in Japan



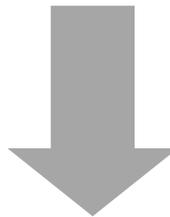
Marketing Approval Holder (MAH)

Using all functions that are possessed by the CMIC Group including development, manufacturing, and sales

Filing/
Approval



Supply



Return, Transfer
or License-out



MHLW

Medical institutions/
Patients

Pharmaceutical
companies



Healthcare Revolution



**Super aging
society**

**Suppression of
medical
expense**

**Personal
health value**

Ethics

**Cost-
effectiveness of
drugs (HTA)**

**Healthy life
expectancy**

Healthcare Revolution

**Precision
Medicine**

**Utilization of Real
World Data (RWD)**

Biomarker

Big Data

**Advancement
of science**

**AI
(Artificial
Intelligence)**

**Disease
prevention**

A paradigm shift in healthcare and medicine

[Past]

- ▶ **Single factor disease**
- ▶ **Treatment only**
- ▶ **Divide** of medicine and healthcare
- ▶ **Hypothesis testing**

[New]

- ▶ **Multifactorial disease**
- ▶ **Cure and prevention**
- ▶ **Seamless**
- ▶ **Comprehensive analysis** based on IoT technology

Selection and Combination

[Conventional drugs]

- ▶ Drugs derived from plants, minerals and animals
- ▶ Nature-derived drugs
- ▶ Low-molecular substance drugs

+

[New technologies]

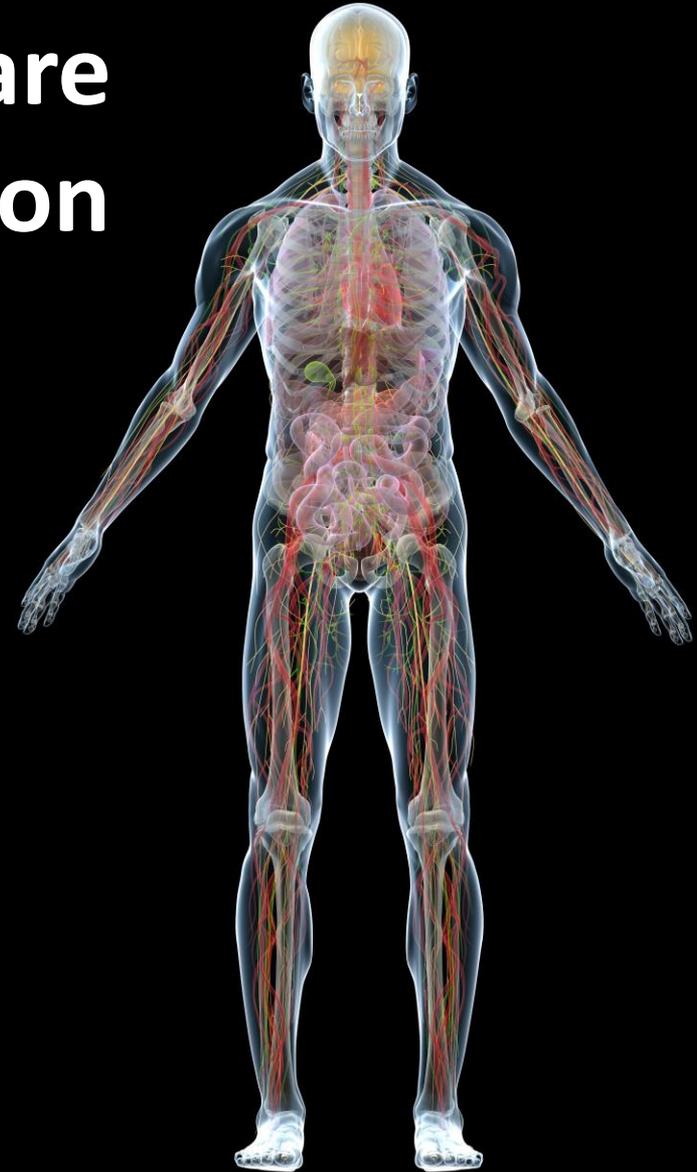
- ▶ Biologics
- ▶ Cell activation drugs
- ▶ Genetically modified drugs
- ▶ Regenerative medicine

Entering the era of complex systems

The new common sense in medicine (system network)



Healthcare Revolution





Project Phoenix 3.0

To be started in April 2018

Towards “Healthcare Revolution”





W&3C

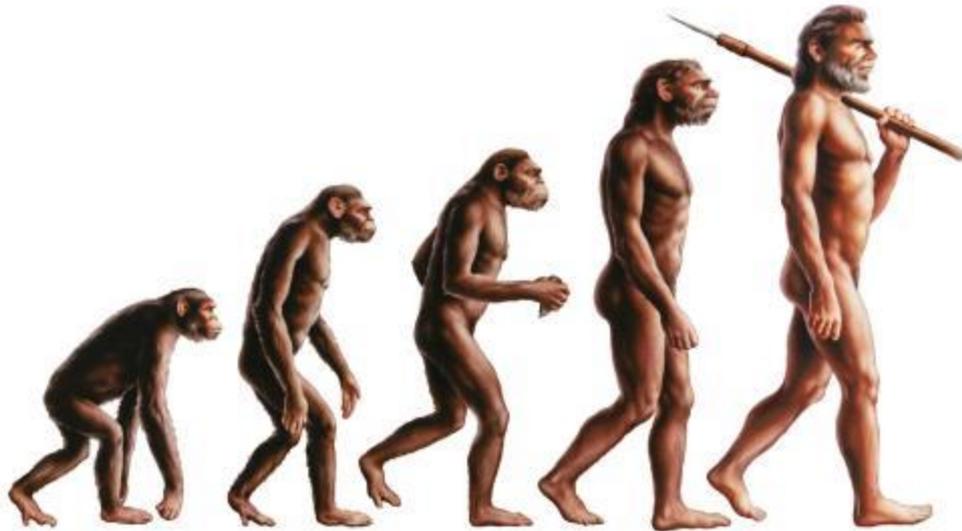
CMIC culture: "Wellbeing"
and the 3 Cs

Keep taking on challenges for the future-CMIC Group

With unchanging determination at heart, we change

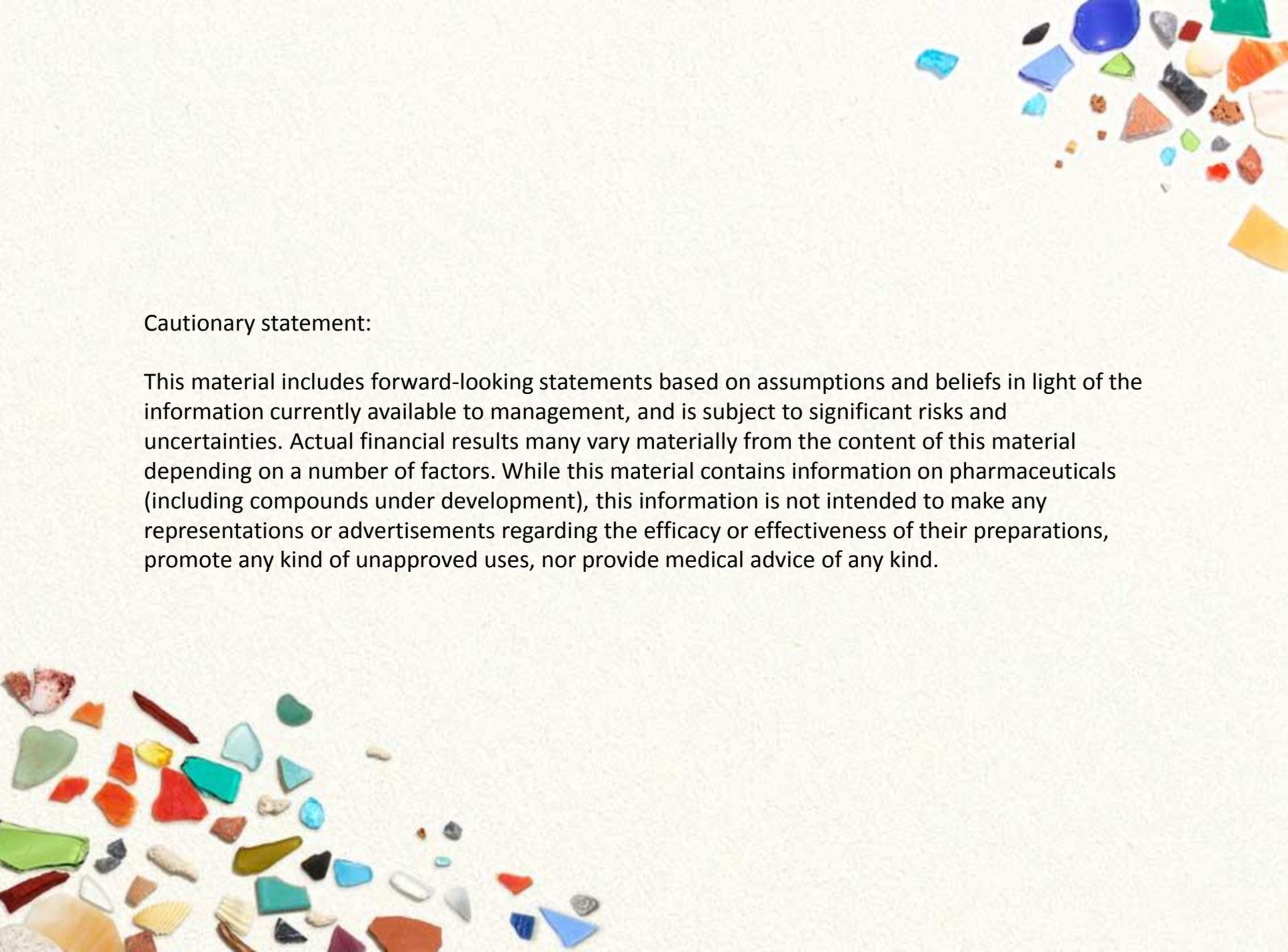


It is not the most intellectual of the species that survives; it is not the strongest that survives; but the species that survives is the one that is able to adapt to and to adjust best to the changing environment in which it finds itself.



Charles Robert Darwin
1809-1882

G H I K L



Cautionary statement:

This material includes forward-looking statements based on assumptions and beliefs in light of the information currently available to management, and is subject to significant risks and uncertainties. Actual financial results may vary materially from the content of this material depending on a number of factors. While this material contains information on pharmaceuticals (including compounds under development), this information is not intended to make any representations or advertisements regarding the efficacy or effectiveness of their preparations, promote any kind of unapproved uses, nor provide medical advice of any kind.