

Overview of Financial Results for 2nd Quarter FY2017

CMIC HOLDINGS Co., Ltd.

May 9, 2017



FY17 2Q Financial highlights

(October 1,2016-March 31,2017)



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 March. 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 Pharma Science Co., Ltd. CMIC Career Co., Ltd. CMIC, Inc. 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.
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 HOLDINGS 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. Healthclick 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. 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 H1 FY2017

Project Phoenix

~25th anniversary – to respond quickly to reforms in the healthcare and pharmaceutical industries~

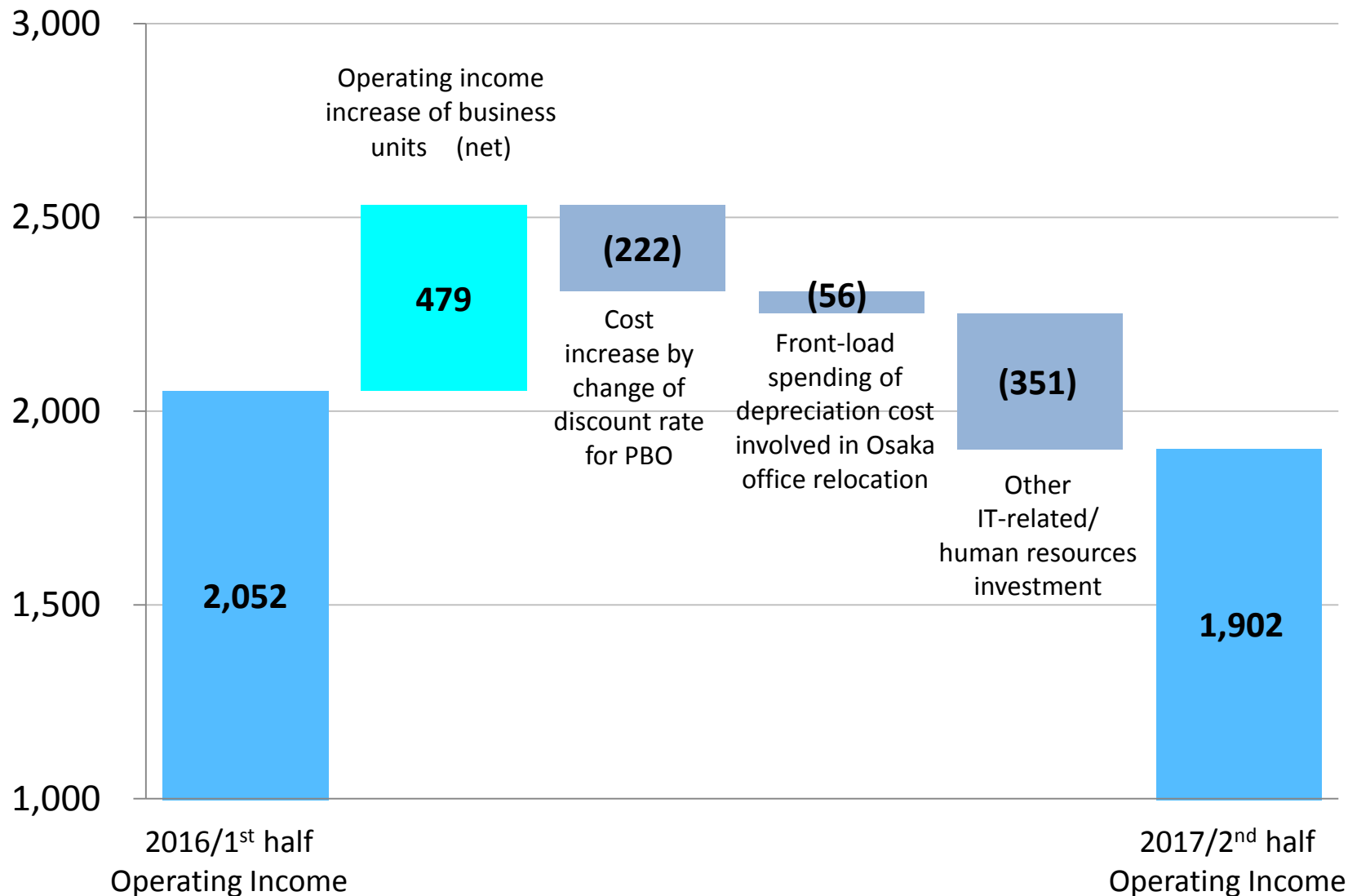
- ✓ CRO Business won new orders for large-scale clinical trial projects
- ✓ CDMO Business strengthened technical capabilities including formulation development
- ✓ CSO Business enhanced multichannel services, and started MSL and contact center operations
- ✓ SMO Business of Healthcare segment achieved significant performance recovery
- ✓ OrphanPacific, Inc. launched DIAZOXIDE Capsules "MSD"

Consolidated income statement (overview)

	2016/H1 (Actual)		2017/H1 (Plan)		2017/H1 (Actual)			
	Amount	Composition ratio	Amount	Composition ratio	Amount	Composition ratio	YoY gap	To plan gap
	(¥ millions)	(%)	(¥ millions)	(%)	(¥ millions)	(%)	(¥ millions)	(¥ millions)
Sales	30,767	100.0	31,800	100.0	31,743	100.0	975	(56)
Operating income	2,052	6.7	1,330	4.2	1,902	6.0	(150)	572
Ordinary profit	1,900	6.2	1,200	3.8	1,888	6.0	(12)	688
Profit attributable to owners of parent	829	2.7	450	1.4	533	1.7	(295)	83
Earnings per share	¥44.36		¥24.06		¥28.54			

Operating income YoY gap analysis

(¥ millions)



Breakdown of Non-operating income and expenses /Extraordinary losses and Income taxes

(¥ millions)

	2016/H1	2017/H1		2016/H1	2017/H1
Non-operating income	79	158	Extraordinary losses	33	366
Foreign exchange gains	-	104	Provision of allowance for doubtful accounts *	-	321
Interest income	13	21	Loss on sales of non-current assets	1	21
Compensation income	21	—	Loss on retirement of non-current assets	20	23
Other	43	32	Impairment loss	11	—
			*Allowance for doubtful accounts was booked for business in Vietnam		
Non-operating expenses	230	171			
Interest expenses	74	70	Total income taxes	912	900
Share of loss of entities accounted for using equity method	48	66	Income taxes - current	972	925
Foreign exchange losses	76	—	Income taxes - deferred	△59	△24
Other	32	34			

Sales & operating income by segment

		2016/H1 Amount (¥ millions)	2017/H1 Amount (¥ millions)	Change (¥ millions)	Percent change (%)
CRO Business	Sales	15,782	16,508	725	4.6
	Operating income	2,693	2,913	219	8.2
CDMO Business	Sales	6,787	6,728	(59)	(0.9)
	Operating income	144	(239)	(383)	-
CSO Business	Sales	3,739	3,452	(287)	(7.7)
	Operating income	330	247	(82)	(25.1)
Healthcare Business	Sales	3,450	4,023	572	16.6
	Operating income	28	616	587	2,071.8
IPM Business	Sales	1,263	1,154	(109)	(8.7)
	Operating income	(16)	(75)	(59)	-
Adjustments	Sales	(256)	(124)	132	-
	Operating income	(1,128)	(1,560)	(432)	-
Consolidated	Sales	30,767	31,743	975	3.2
	Operating income	2,052	1,902	(150)	(7.3)

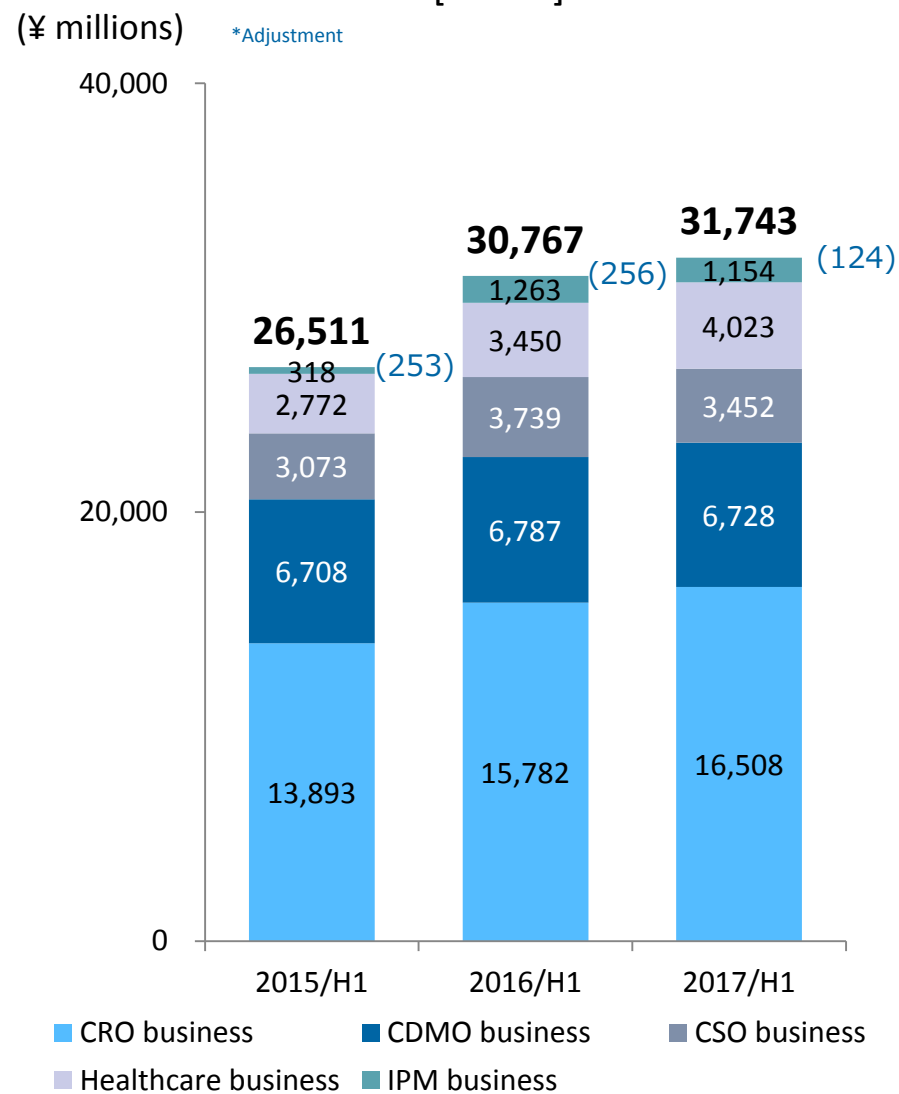
Orders received / Backlog

	2016/H1		2017/H1			
	Orders received	Backlog	Orders received	Percent change	Backlog	Percent change
	(¥ millions)	(¥ millions)	(¥ millions)	(%)	(¥ millions)	(%)
CRO Business	14,608	41,902	24,938	70.7	54,067	29.0
CDMO Business	7,645	4,116	7,389	(3.4)	3,999	(2.9)
CSO Business	2,288	5,641	2,097	(8.4)	4,239	(24.9)
Healthcare Business	3,705	9,194	3,107	(16.1)	8,596	(6.5)
Total	28,248	60,855	37,532	32.9	70,903	16.5

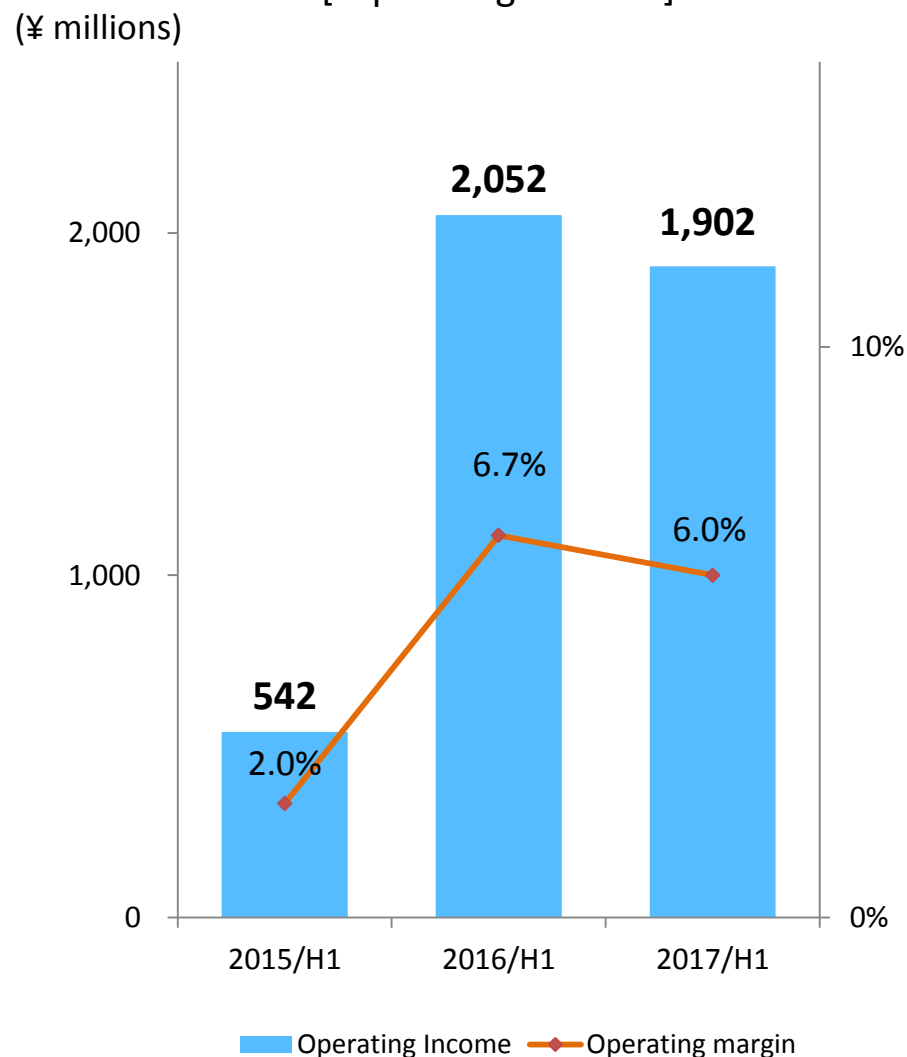
- Accounts for only the backlog of firm CDMO business orders. There is customer demand for scheduled orders but these are different from firm orders so we have not included these in the backlog.
- Order status is not included for IPM Business because its business conditions are different from those of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

Trend in consolidated sales & operating income

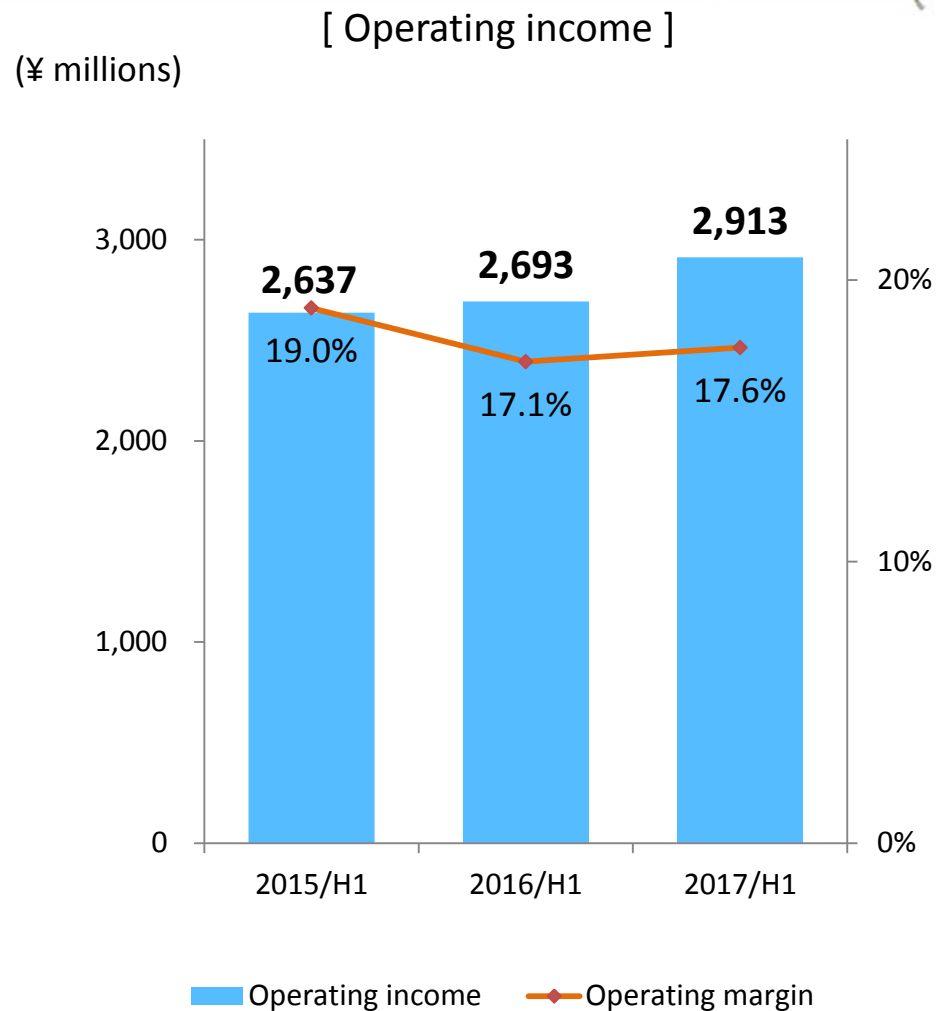
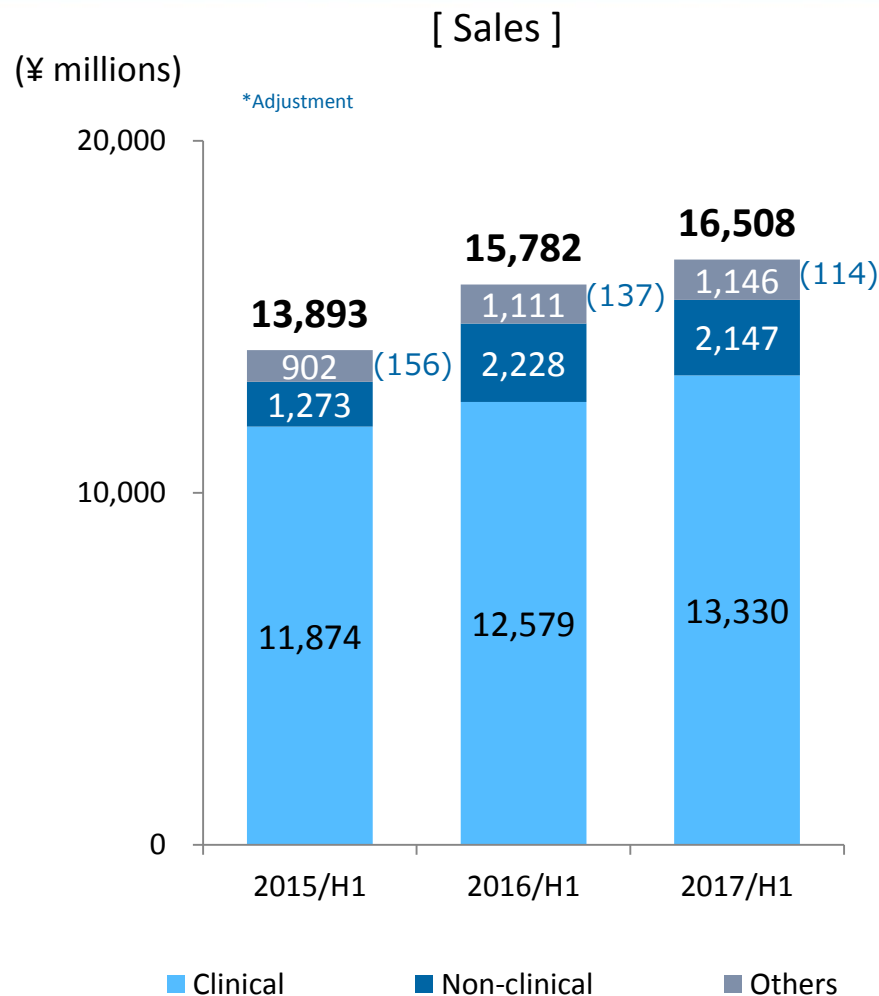
[Sales]



[Operating income]

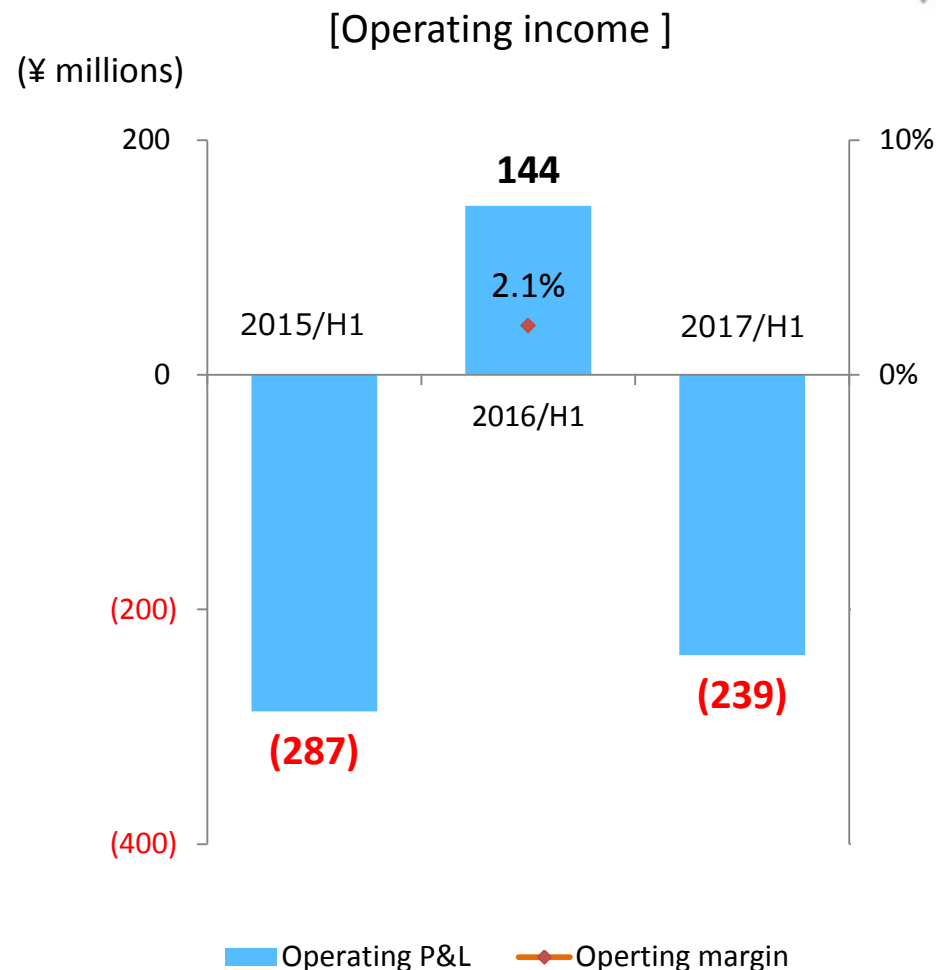
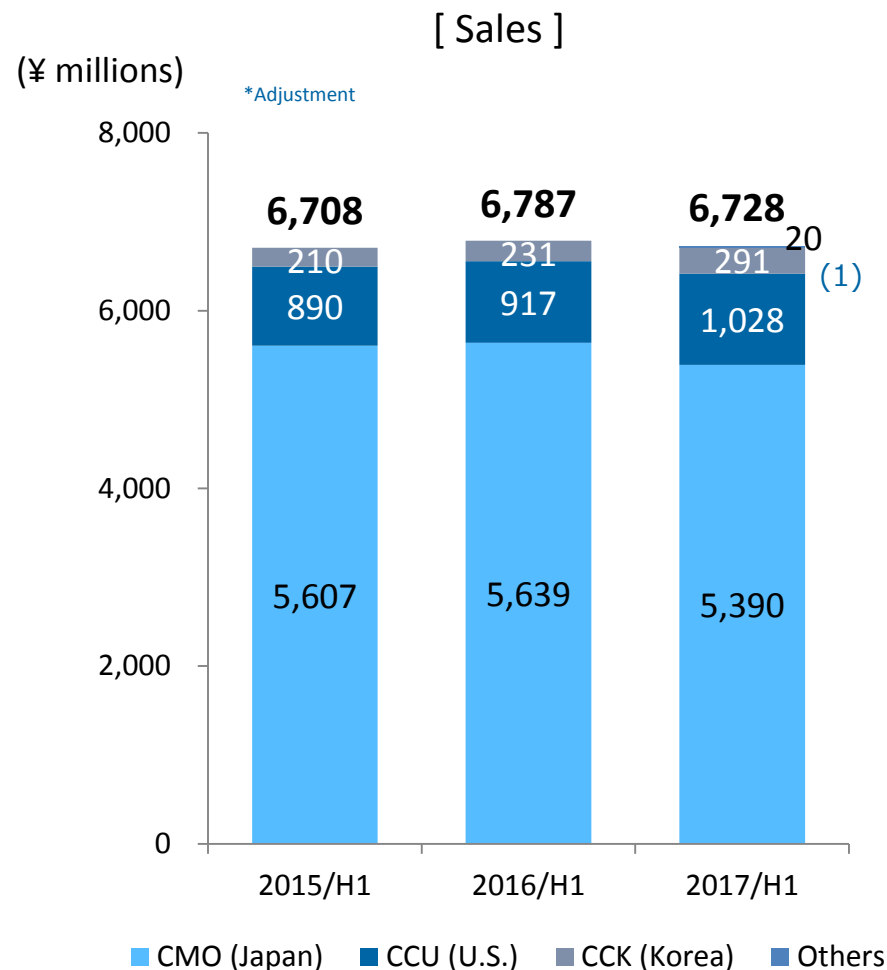


Contract Research Organization (CRO) Business



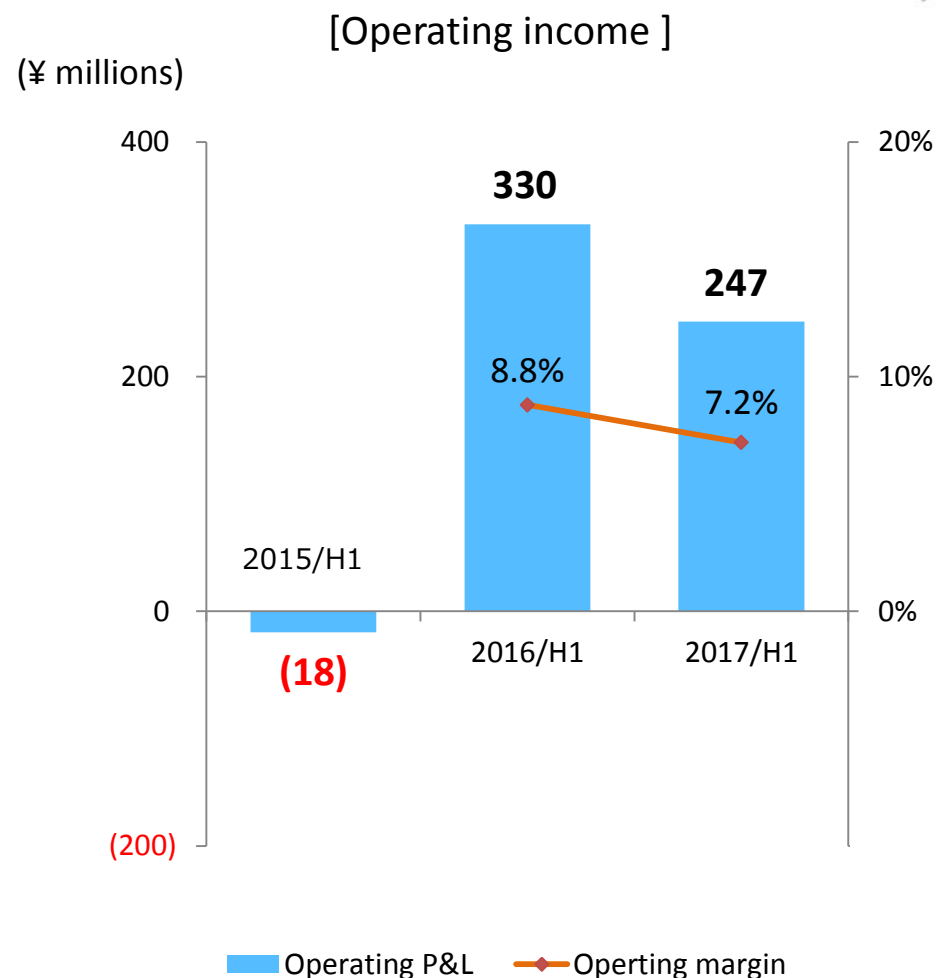
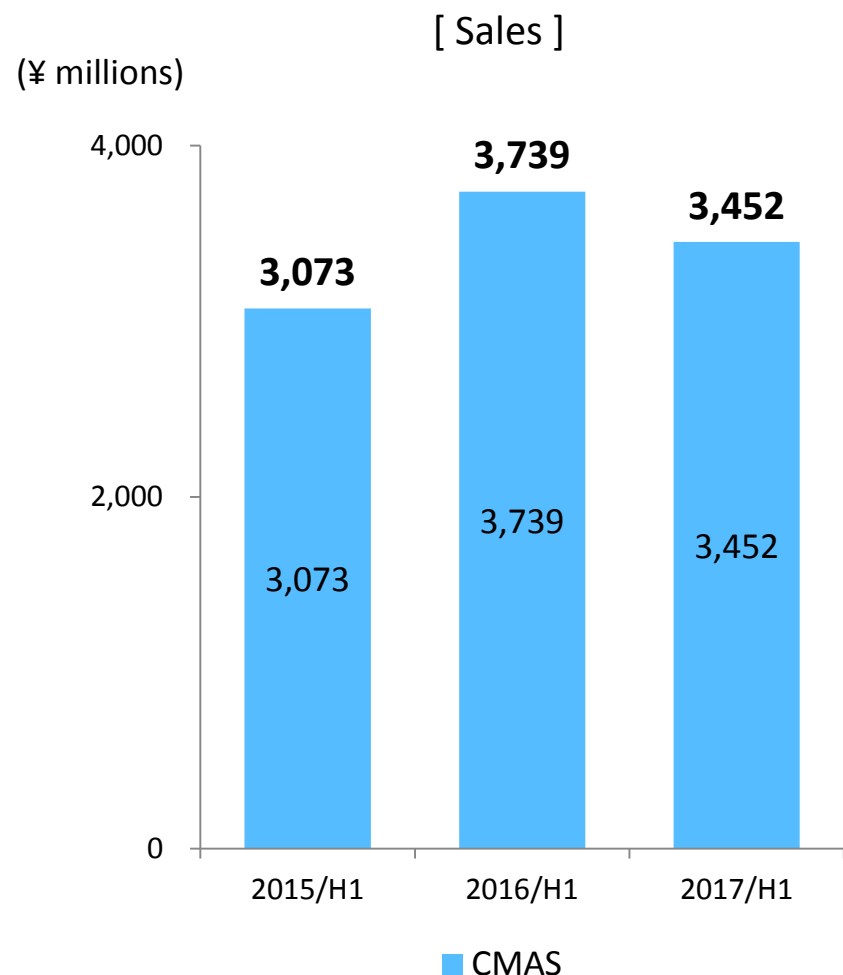
Work to develop human resources with the aim of securing human resources based on robust demand, further expertise, and improving quality. Build a support system related to the field of regenerative medicine. Strengthen U.S.-Japan ties in non-clinical services such as support for companies in the U.S. market. Sales and operating income exceeded those of the previous year on growth in new orders and existing contracts.

Contract Development Manufacturing Organization (CDMO) Business



Built a system for low-cost production, increasing new contracts for generic drugs by working to transition to a price-competitive, low-cost structure. Though we have recorded a decrease in sales compared to the same period in the previous year and incurred an operating loss because of a temporary fall in production resulting from clients' inventory adjustments, the forecast for the full year is unchanged since the beginning of the period due to recovery of new orders and contract manufacturing of existing projects starting from the second half of the fiscal year.

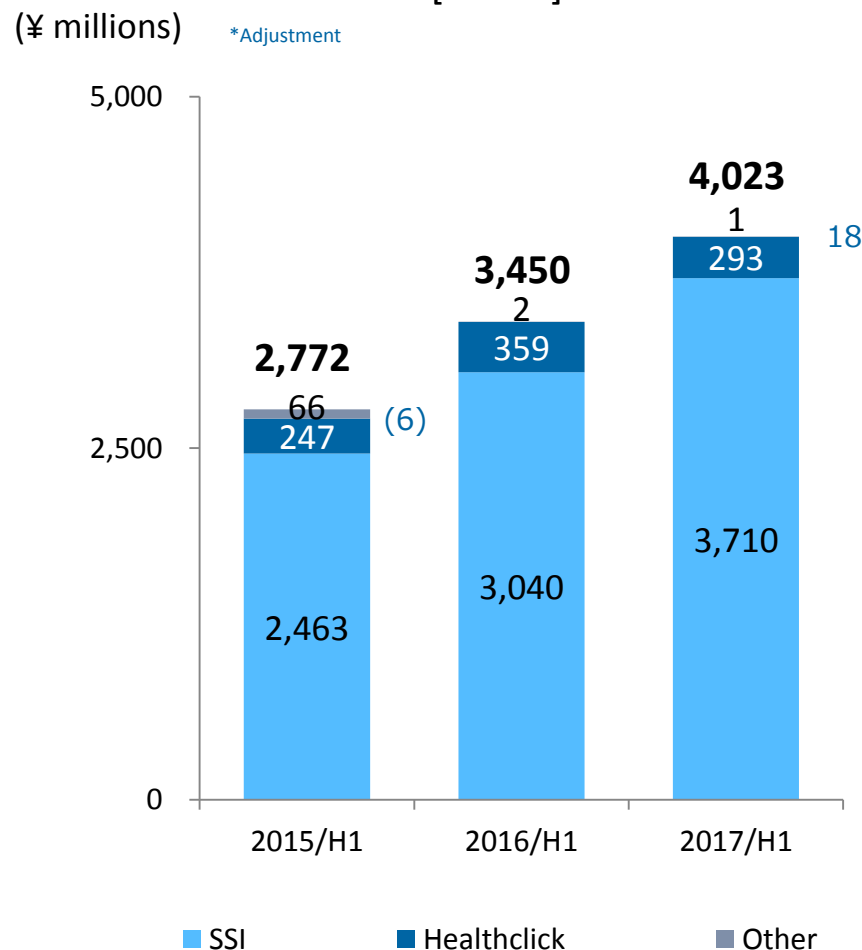
Contract Sales Organization (CSO) Business



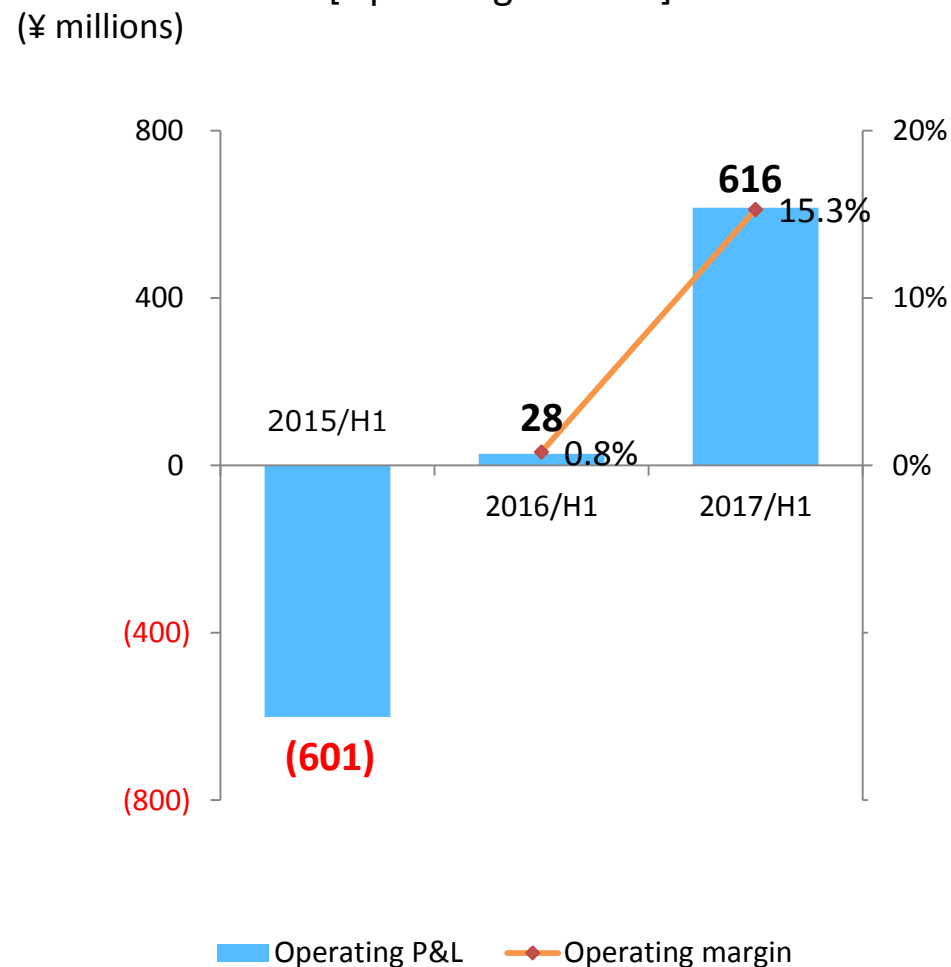
CMIC Ashfield Co., Ltd. has worked steadily to strengthen its capacity to meet demands and move through existing projects. They are also working to expand market share by improving support for client needs, such as by providing multichannel services. Although sales and operating income came in lower than those during the same period of the previous year due to the impact from the temporary adjustment of outsourcing needs, the forecast for the full year operating income is unchanged since the beginning of the period due to cost reduction.

Healthcare Business

[Sales]

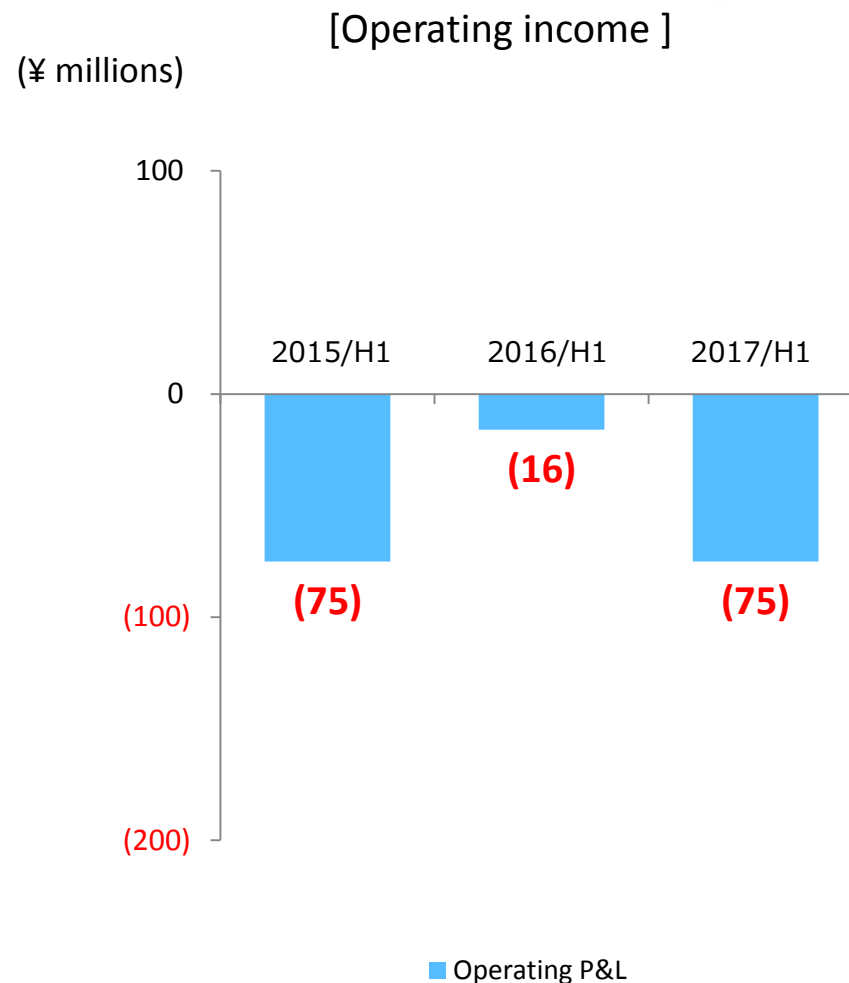
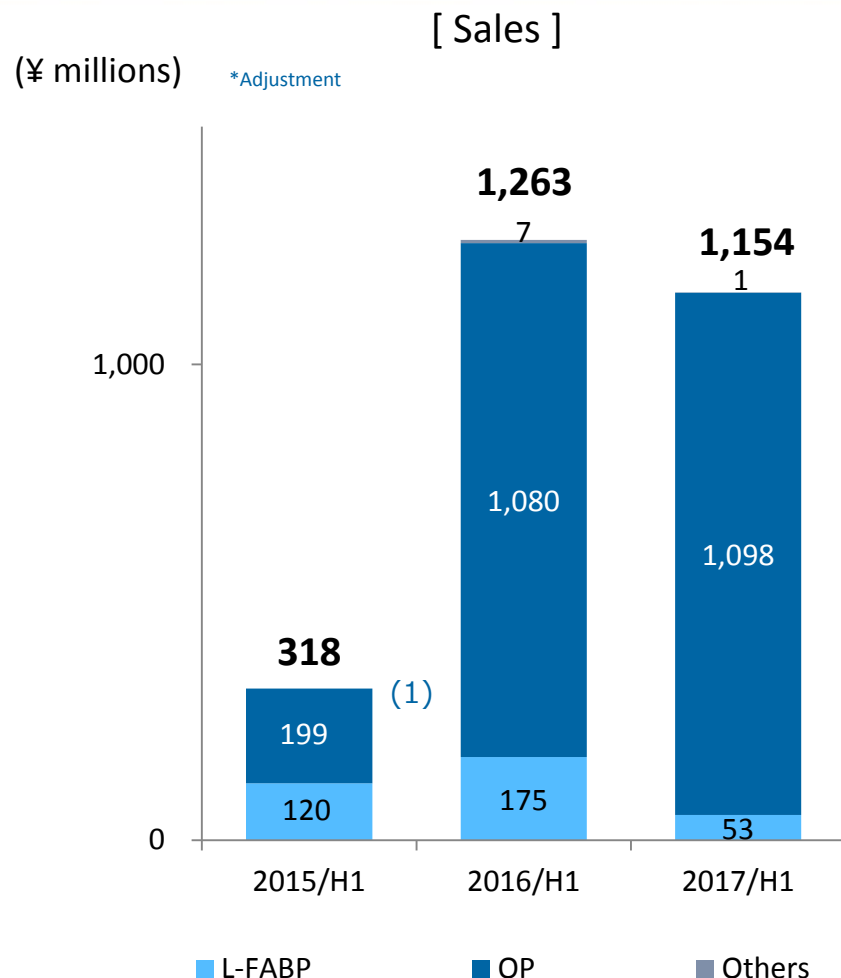


[Operating income]



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 foundations of IPM Business by launching 5 orphan drugs including products developed in-house and concluded sales transfer agreement with a pharmaceutical company. Diagnostics business started selling simple test kits (Dip-test) for the in vitro diagnostic drug. Though sales and operating profits came in lower versus the same period of the previous year mainly due to decrease of diagnostics contract research projects from AMED , they are now focusing on business development activities to expand their business by providing new solutions.

Balance sheet (assets)

(¥ millions)

80,000

- Cash equivalents
- Trade receivables
- Inventory
- Other current assets
- Fixed assets

60,000

40,000

20,000

0

55,861

5,804

10,787

5,439

4,251

29,578

2015/9

59,104

5,069

10,731

5,285

3,713

34,305

2016/9

63,723

5,747

11,802

5,224

3,726

37,222

2017/3

Total assets +4,618

■ Cash equivalents +677

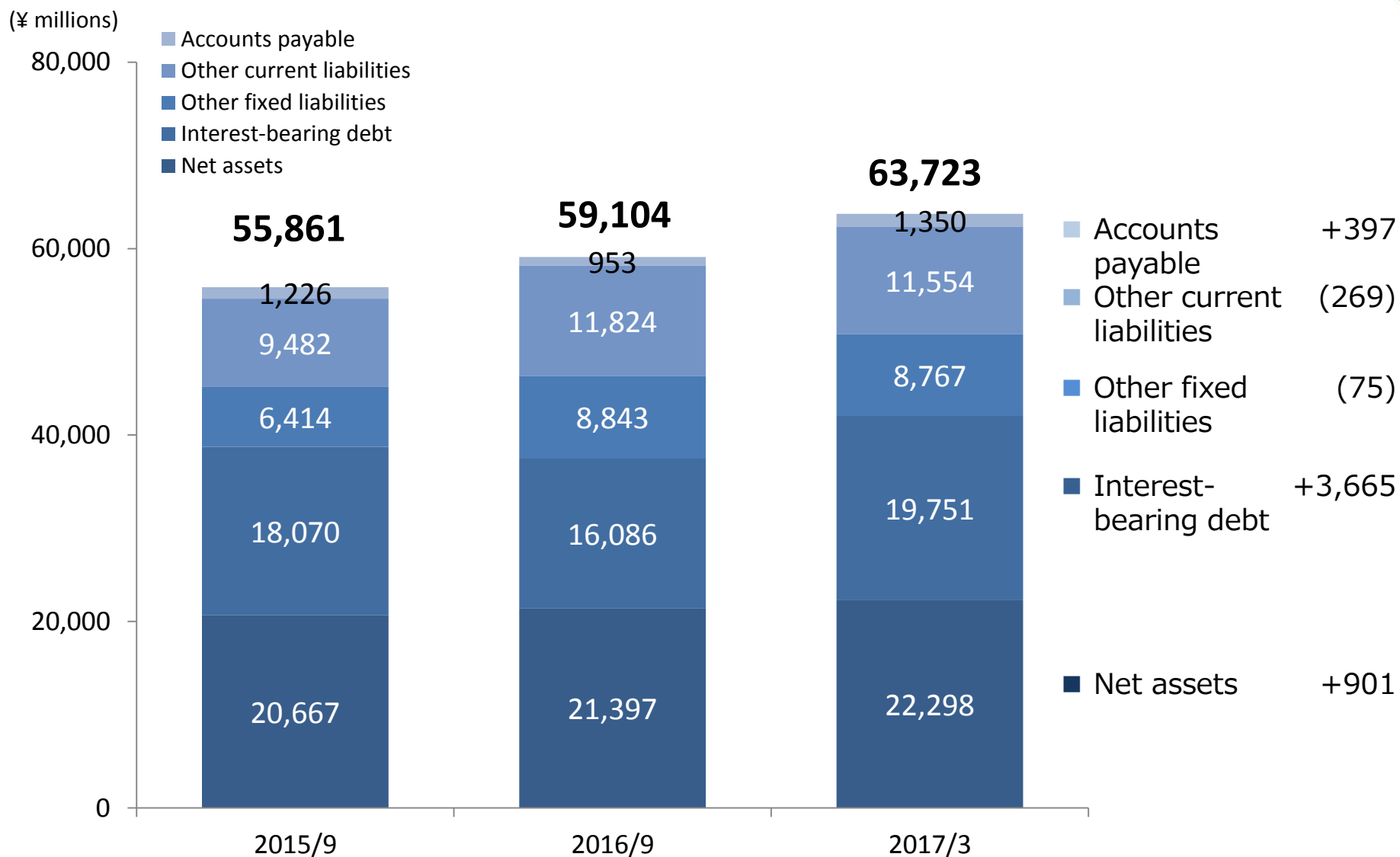
■ Trade receivables +1,070

■ Inventory (61)

■ Other current assets +13

■ Fixed assets +2,917

Balance sheet (liabilities and net assets)



Cash Flows

	2016/H1	2017/H 1	(¥ millions) Increase (decrease)
Cash flow from operating activities	1,988	1,257	(731)
Cash flow from investing activities	(2,072)	(3,932)	(1,859)
Cash flow from financing activities	1,397	3,352	1,954
Translation difference of cash and cash equivalents	(41)	103	144
Change in cash and cash equivalents	1,273	780	(492)
Cash and cash equivalents at beginning of period	5,638	4,946	(692)
Increase in cash and cash equivalents from newly consolidated subsidiary	—	1	1
Cash and cash equivalents at end of period	6,911	5,728	(1,182)

[Key factor]

(Cash flow from operating activities)

- Decrease in current term net income
- Increase from payment of corporate tax

(Cash flow from investing activities)

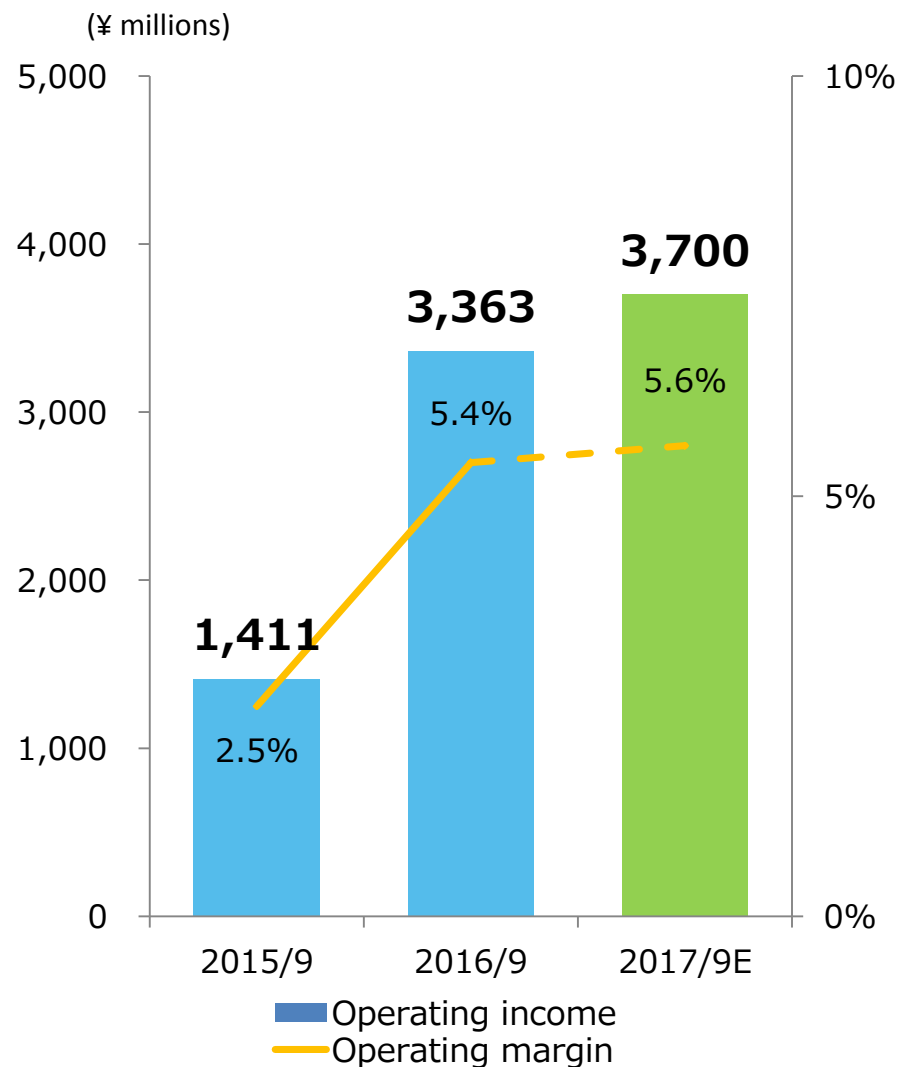
- Outflow from acquisition of tangible and intangible fixed assets
- Outflow from acquisition of investment securities

(Cash flow from financing activities)

- Inflow from the long-term loans from financial institutions

Forecast for FY ending Sept. 2017

	2016/9 Actual (¥ millions)	2017/9 Forecast (¥ millions)	Change (%)
Sales	62,039	66,500	7.2
Operating income	3,363	3,700	10.0
Ordinary income	2,989	3,420	14.4
Profit attributable to owners of parent	878	1,200	36.5





CMIC Group Business Strategies

CMIC HOLDINGS Co., Ltd.

**Kazuo Nakamura,
Chairman & CEO**





Revolutionary Change in the Pharmaceutical Industry Structure



The environment surrounding the pharmaceutical industry (Japan)

Change and diversification of pharmaceutical business model

- Medical expenditure curtailment (financial difficulties, population aging, surge in new drug development costs, complexity of target diseases)
- Challenges faced for long-listed products (NHI price revisions, promotion of generic drugs, importance of data)
- Manufacturing capacity issues for generic drugs
- Foreign pharmaceutical companies entering the Japanese market without having footholds in Japan (EU, USA, China, India, Korea)
- Global expansion of Korean biopharmaceuticals (biosimilars)
- Changes in R&D (venture companies/collaboration with academia/outourcing)
- Weakened domestic R&D capabilities/delay in globalization
- New technologies including regenerative medicine/cell therapy, gene therapy, biomarker, and evaluation method
- Addressing the unmet medical needs/orphan drugs
- Stable supply of high-quality medicines

Domestic market environment for CxO business

CRO

- Annual market growth: 9%
- Market size: 200 billion JPY by 2020
- Increasing number of global trials
- Highly specialized therapeutic areas including Oncology, Immunology, and Cell Therapy
- Provision of comprehensive solutions
- KSF: Quality, cost, speed, flexible resources, English proficiency, global operations

CDMO

- Annual market growth: 6%
- Market size: 700 billion JPY by 2020
- Solutions for generic drugs/long-listed products
- International standards/global expansion
- Formulation development capabilities, new business models
- KSF: Quality, stable supply, technical capabilities, cost, flexibility, creation of new business models

CRO : CMIC estimates based on Japan CRO Association 2016 market data/ Frost & Sullivan 2016 market research/PMDA clinical trial submissions and CRO market growth trend

CDMO : CMIC estimates based on Frost & Sullivan 2016 Japan CDMO market size forecast data/2015 Yano Research CMO market data

Domestic market environment for CxO business

CSO

- Annual market growth: 3%
- Market size: 65 billion JPY by 2020
- Optimization of commercial solutions using ICT
- Provision of multi-channel services
- Medical Affairs, Medical Science Liaison
- KSF: Flexible resource management, multi-channel service, cost optimization

SMO

- Market growth: Flat
- Market size: 35 billion JPY by 2020
- Industry reorganization
- Increasing number of in-house CRC
- Site selection, patient recruitment
- KSF: Quality Assurance, Strength in planning and proposals

CSO : CMIC estimates based on benchmarking of Japan CSO Association 2016 market size data/MR outsourcing rate (12%) in the US market

SMO : CMIC estimates based on Yano Research 2015 market size data and business trends of competitors

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)

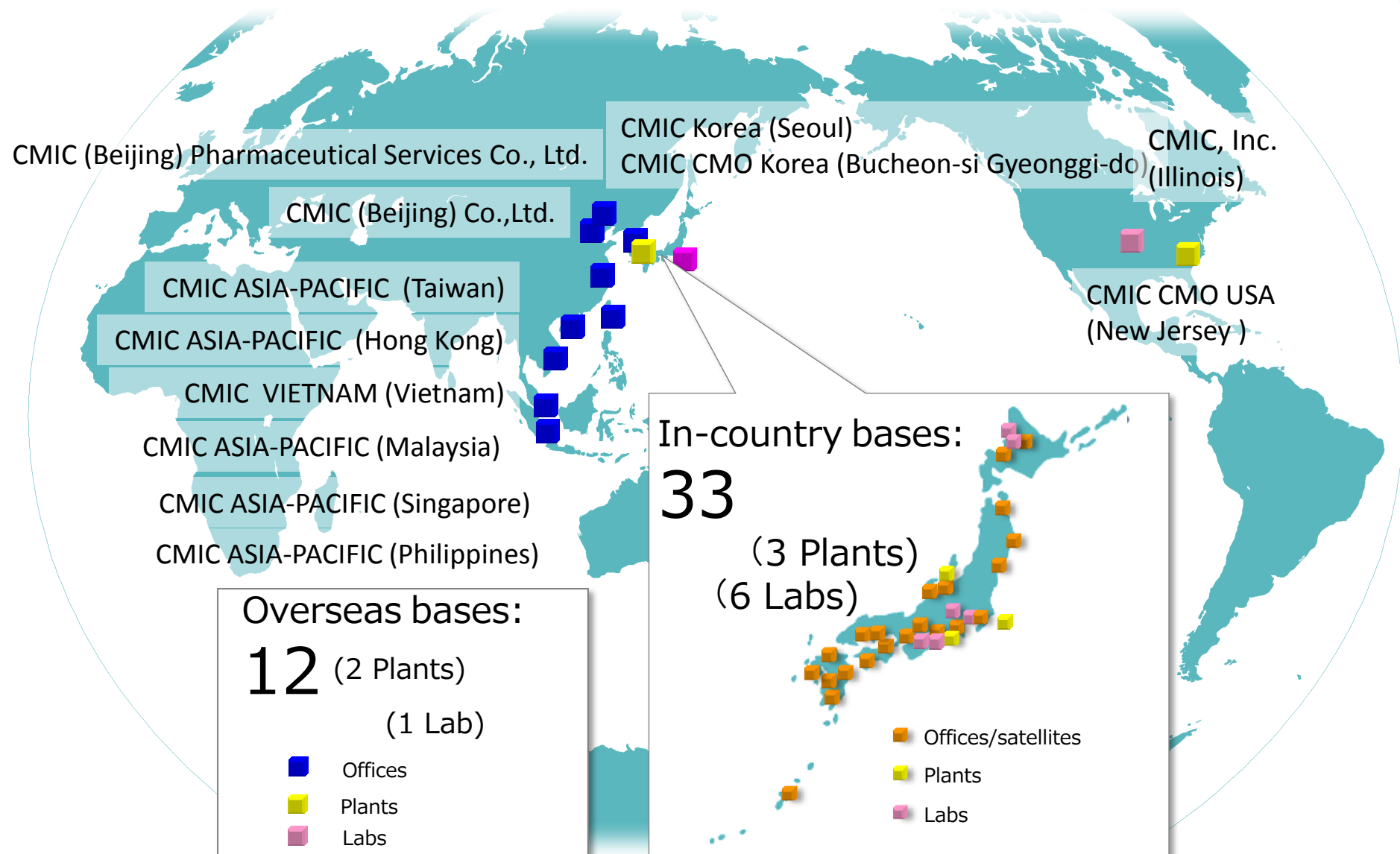
Pharmaceutical company that exists for the benefit of pharmaceutical companies

CRO business

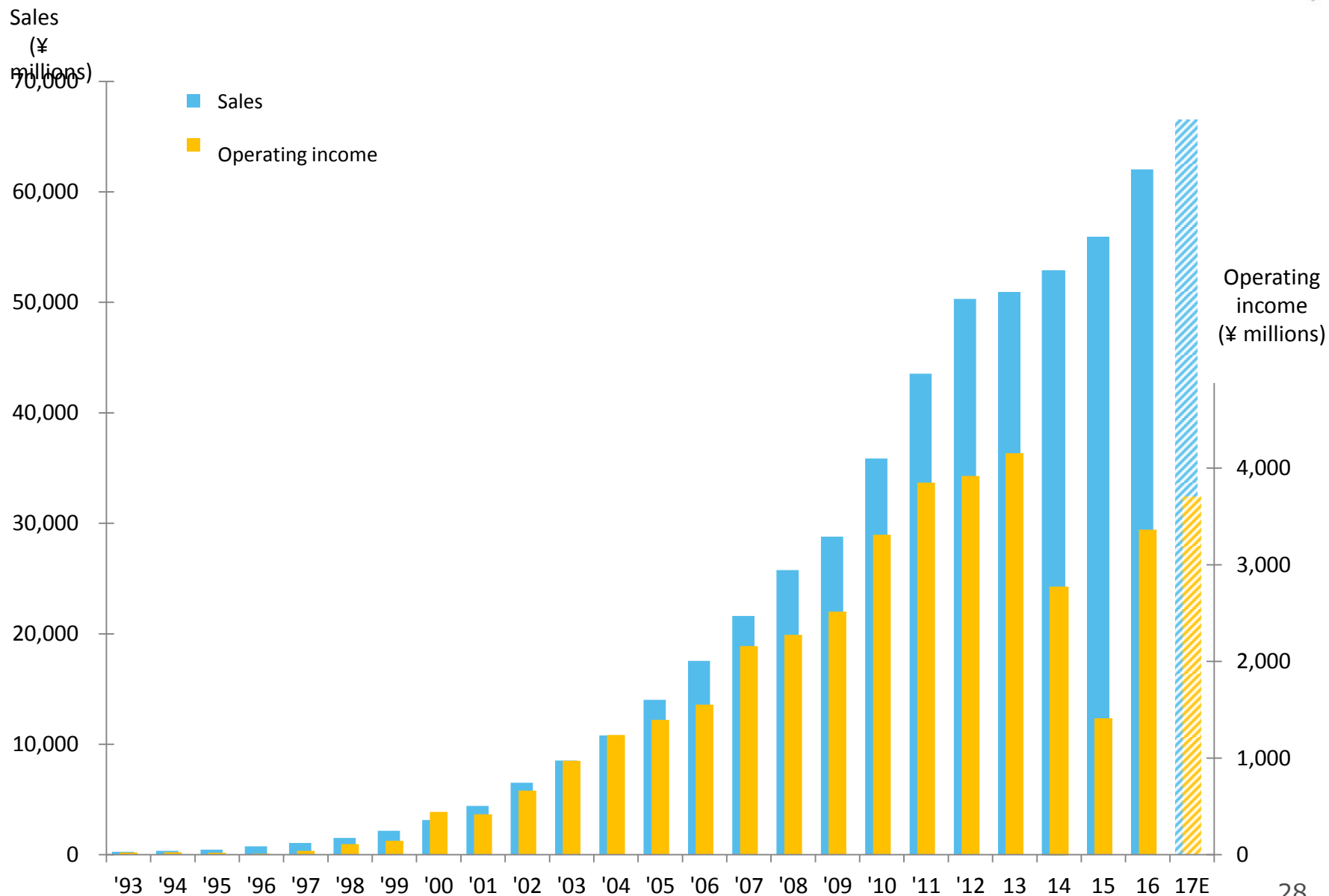
(Contract Research Organization)

Drug development support

CMIC Group Global Coverage



Trend in sales & operating income



Growth targets for each business

CRO

Asia's No.1 CRO

- Addressing globalization and diverse customer needs
- Becoming a strategic partner

CDMO

Establishing a stable profit structure

- Optimization of services, repositioning (CMC, Development, Formulation Design, Manufacturing, Supply Chain Management)
- Globalization, partnership with foreign companies

CSO

Strengthening on-going partnership with Ashfield K.K.

- Expansion of market share
- Multi-channel commercial solutions

HC

Quality-oriented SMO

- Expansion of SMO share
- Establishing a new business in the healthcare arena

IPM

Pharmaceutical company that exists for the benefit of pharmaceutical companies


- Providing support for the companies changing their business models
- Providing support for the companies entering the Japanese market



IPM Business

Innovative Pharma Model

Pharmaceutical company that exists for the benefit of
pharmaceutical companies



IPM Business Objectives

Business solutions for pharmaceutical companies

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

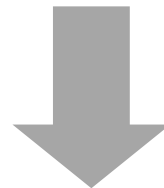
- Low performing products of pharmaceutical companies
- Launching academia and Bio-venture drug seeds

Licenses held by CMIC Group

Licenses		Holder
Drugs	First-class drug marketing license	CMIC HOLDINGS Co., Ltd. and OrphanPacific Inc.
	Second-class drug marketing license	CMIC HOLDINGS Co., Ltd. and OrphanPacific Inc., CMIC CMO Co., Ltd.
	License for manufacturer of drugs	CMIC CMO Co., Ltd./Shizuoka, Toyama, Ashikaga
Medical devices	First class medical devices marketing license	CMIC Co., Ltd.
	License for manufacturer of medical devices	CMIC CMO Co., Ltd./Shizuoka
Diagnostics	Diagnostic marketing license	CMIC HOLDINGS Co., Ltd.
Cosmetics	Cosmetics marketing license	CMIC CMO Co., Ltd./Toyama
	License for manufacturer of cosmetics	CMIC CMO Co., Ltd./Toyama
Quasi-drugs	Quasi-drugs marketing license	CMIC CMO Co., Ltd./Toyama
	License for manufacturer of quasi-drugs	CMIC CMO Co., Ltd./Toyama

IPM Business – Domestic pharmaceutical companies

Domestic pharmaceutical companies



Low performing products of pharmaceutical companies

Marketing Approval Holder (MAH)



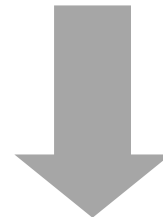
Using all functions that are possessed by the CMIC Group including development, manufacturing, and sales

**MA
Transfer/
Notification**



MHLW

Supply



**Medical institutions/
Patients**

IPM Business - Overseas pharmaceutical companies that have no foothold in Japan

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



Marketing Approval Holder (MAH)

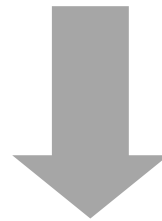
Using all functions that are possessed by the CMIC Group including development, manufacturing, and sales

Filing /
Approval



MHLW

Supply



Medical institutions/
Patients

Return, Transfer
or License-out



Pharmaceutical
companies



IPM Case: Foot nail repair solution

Target: Foreign pharmaceutical company that has no foothold in Japan (value maximization in terms of time)

- Approved as a medical device overseas and cosmetic product in Japan
- Business roll out as MAH (Marketing Authorization Holder)



Nationwide release in
January 2017

IPM Case: Sales transfer of DIAZOXIDE Capsules

Sales transfer of DIAZOXIDE Capsules 25 mg “MSD” to OrphanPacific Inc. as of April 1 2017



Medicine to treat "hyperinsulinemic hypoglycemia"

The only medicine in Japan that has been approved for the indication of "hyperinsulinemic hypoglycemia" associated with congenital hyperinsulinemia, insulinoma, etc.

674 subjects*

* The cumulative number of cases submitted for safety assessment during the specific use results survey (2008/7-2016/4).

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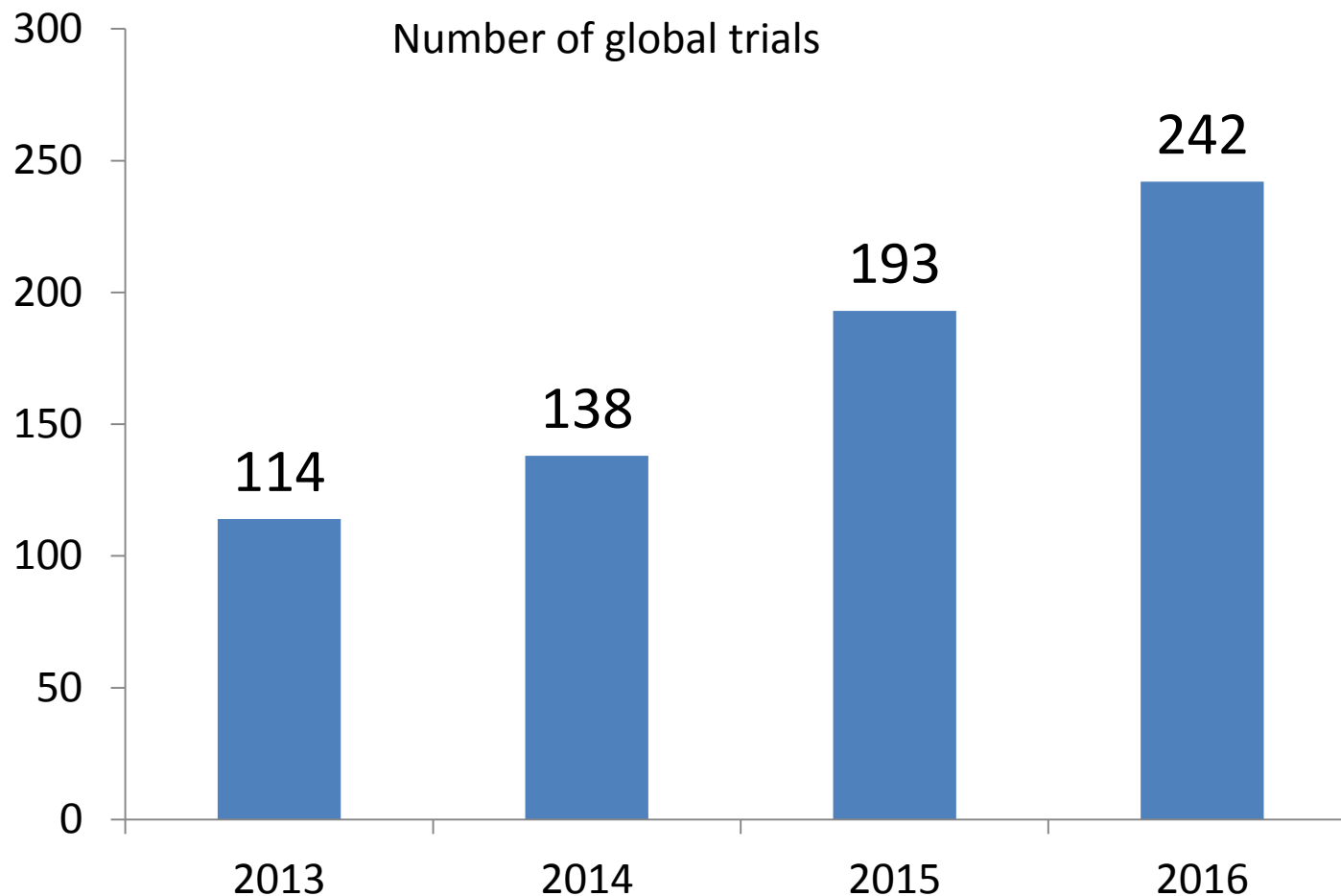
CRO Business

Drug development services

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Environment surrounding the CRO industry

Despite the decrease of Japan local trials, **the number of global trials is increasing**



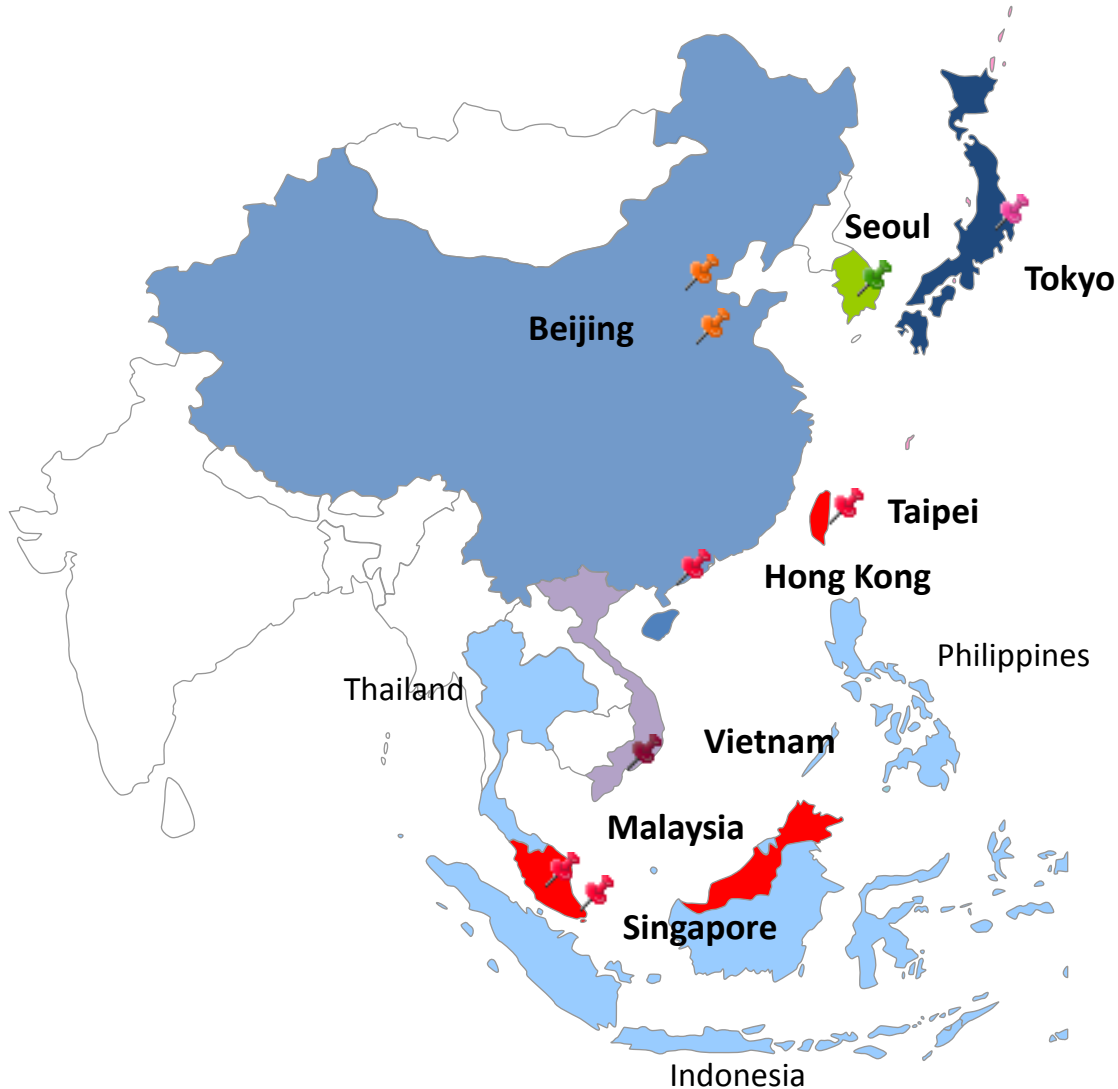
Source: Japan CRO Association Annual Report

Globalization of CRO Business

Transitioning from “West meets East” to “East meets West”

- ▶ Further enhancement of business operation bases in Asia
- ▶ Project management base is scheduled to launch in the United States
- ▶ Business alliance with other CROs in Europe and the United States
- ▶ Establishment of seamless operations between Japan and US as analytical CRO

Our bases in Asia



 **CMIC HD / CMIC: Japan**

 **CMIC Korea: Korea**

 **CMIC Beijing: China**

 **CMIC Asia-Pacific**

- Singapore (HQ)
- Taiwan
- Malaysia
- Hong Kong
- Philippines

Field-based Locations

- Thailand
- Indonesia

 **CMIC Vietnam: Vietnam**



Non-clinical CRO Business

Analytical laboratory for Non-clinical CRO Operations



- ▶ USA
(CMIC, Inc.)



- ▶ Ishikari
QA



- ▶ Nishiwaki
Bioanalysis

Seamless coordination between labs in the United States and Japan

New animal testing facility

All suites are fully operating after April



We consider animal protection and welfare
[AAALAC \(Association for Assessment and Accreditation of Laboratory Animal Care\)](#)

Fully accredited: Feb. 2007
(Accreditation renewed Mar. 2013)

We conduct safety testing related to regenerative medicine such as tumorigenicity testing*

*Test which confirms whether xenogeneic cells transplanted in the body have become cancerous

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CDMO Business

**Formulation development and
manufacturing support**

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Size of global CDMO business market

CDMO market is expected to continue to grow at a rapid pace worldwide in the future

EU CMO market

2015 ¥ 2.0 trillion

2020 ¥ 2.6 trillion

CAGR 5.6%

2015 ¥ 0.5 trillion

2020 ¥ 0.7 trillion

CAGR 5.7%

2015 ¥ 2.9 trillion

2020 ¥ 4.3 trillion

CAGR 7.8%

CMO global market

2015 ¥ 7.27 trillion

2020 ¥ 10.87 trillion

CAGR 8.4%

APAC CMO market

2015 ¥ 2.0 trillion

2020 ¥ 3.6 trillion

CAGR 12.2%

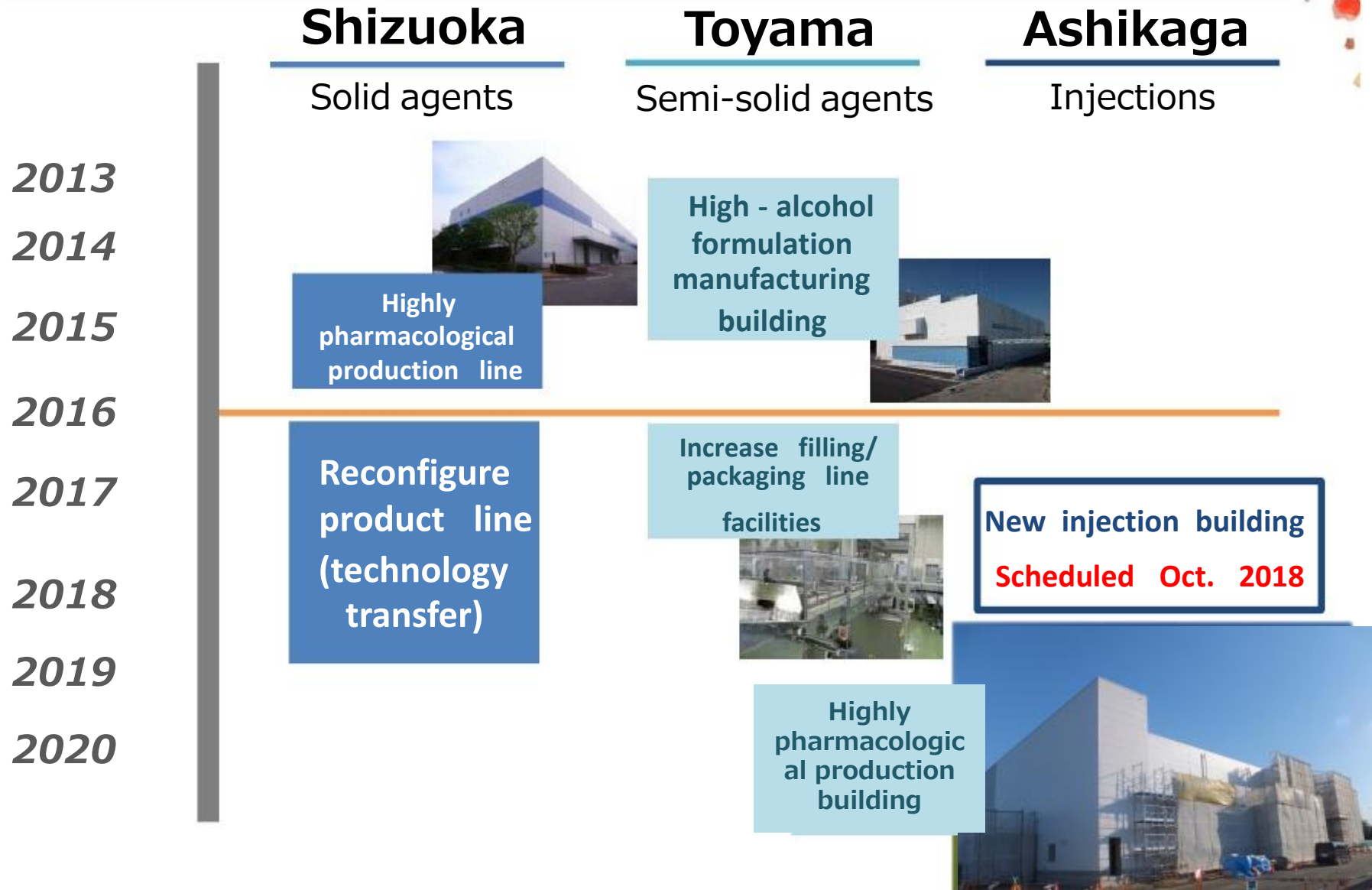
CDMO business environment paradigm shift

Type of company	Current situation
New drug manufacturers	Streamlining R&D/Manufacturing units Selling long-listed products or proactive outsourcing to CDMO <ul style="list-style-type: none">▶ Business model change▶ Stable supply of long-listed products▶ Increased outsourcing of all processes
GE manufacturers	Lack of production equipment and manpower <ul style="list-style-type: none">▶ Promotion of the use of generic drugs, reduction in the NHI drug prices▶ Use of CDMO following globalization▶ Product selection, formulation design
Academia/ Bio-ventures	Necessity of strategic partner <ul style="list-style-type: none">▶ Formulation, IMP manufacturing, commercial production

Seamless new drug/generic drug/new formulation development model

	Pre-clinical study	Clinical trial application	Clinical trial/BE study	Stability test	Approval application	Commercial production
DS Supplier	DS supplier	CMC	DS supply	DS supply	Manufacturing method	
CMIC Pharma Science	DS analysis Development	CMC	Drug concentration analysis (BE)		Analytical method	Technology transfer
CPhS Bio Research Center	Non-clinical study	Non-clinical			Non-clinical	
CDMO Formulation Development	DP development DP analysis Development	CMC	IMP manufacturing	DP manufacturing Stability test	Manufacturing method	Technology transfer
Regulatory consultation		Filing consultation CMC			Filing consultation CMC	
CRO			Clinical trial /BE study		Clinical	
CDMO						Technology transfer Manufacturing

Strategic capital investment



Overview of new injection building

[Background]

- ▶ Advanced production technology and global standards (PIC/S *1 and Japan-US-EU GMP*2 compliant)
- ▶ Accommodates high pharmacological activity and organism-derived preparations
- ▶ Expand market of anti-cancer agents

Scheduled to be built and operating in Ashikaga Plant in Oct. 2018



*1: International framework to promote shared manufacturing, the formulation of quality control standards, and inspection in the drug field

*2: Standards on drug manufacturing and quality control stipulated in the U.S., Japan, and Europe

CMIC CMO USA Corporation (CCU)



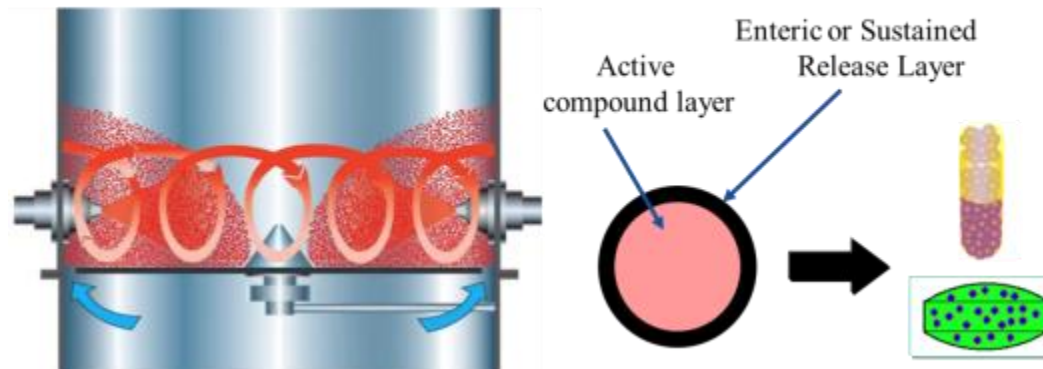
**Specialized CDMO
(New Jersey, USA)**



Particle coating with advanced fluid bed granulating technology

- ▶ Orally disintegrating tablet (taste masking technologies)
- ▶ Extended-release formulations

Mechanism of Process





Establishing corporate culture

CMIC'S CREED

With unchanging determination at heart,
we change



Since we are at turning point, our needs are increasingly sophisticated and diversified. To respond to them, we need to transform ourselves. But, there's one thing that should not change:

“CMIC'S CREED”.

“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






W&3C

CMIC culture: "Wellbeing"
and the 3 Cs

Thank you for your attention.


With unchanging determination at heart, we change



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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.

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