

## Overview of Financial Results for FY2023 2<sup>nd</sup> Quarter/1H

CMIC HOLDINGS Co., Ltd. May 11, 2023



# **Overview of Financial Results**

CMIC GROUP CFO Wataru Mochizuki



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## **CMIC Group Business**







## **CMIC Group Network**





# Focus Activities of Mid-term Management Plan (FY2022-25)

## **Evolution of healthcare business**

Comprehensive support for disease prevention, treatment R&D, and marketing

Contribution to sustainable society through services with high social benefits



## **Progress of 2<sup>nd</sup> quarter of FY2023**

## **Evolution of healthcare business**

- > Expansion of support for local governments
  - Comprehensive support for measures against COVID-19 infections, ranging from infection prevention to post-infection follow-up
  - New solutions to local government / municipalities
- Strengthening our digital platform with the aim of increasing the individuals' health values
  - Business development centered on "nanacara", a support platform for patients and families
  - New business developed with OKEIOS Inc. utilizing personal data









## **Progress of 2<sup>nd</sup> quarter of FY2023**



Comprehensive support for disease prevention, treatment R&D, and marketing

- Comprehensive support from drug development, manufacturing, to sales and marketing - PVC (Pharmaceutical Value Creator) Model -
  - Consulting for entering the Japanese market and entering the healthcare field from other industries
  - Projects for efficacy and safety evaluation and analysis in cutting-edge areas where modalities are diversifying
- > Support combining manufacturing, marketing, and other permits with PVC's value chain
  - Clinical trials in Japan for a treatment for urea cycle disorders

#### \*Urea Cycle Disorders (UCD)

A congenital deficiency of an enzyme in the urea cycle of the liver results in hyperammonemia, a failure to metabolize ammonia



## **Progress of 2<sup>nd</sup> quarter of FY2023**

Contribution to sustainable society through services with high social benefits



- Co-sponsorship of the 14th "International Children's Drawing Contest" Presentation of the 19th "Society Prize (CMIC Prize) of the AIDS Society of Japan" Sponsoring "Rare Disease Day 2023"
- Support for athletes with disabilities

## **Consolidated income statement (overview)**



	FY2022 Q2		FY2023 Q2			
	Amount	Composition ratio	Amount	Composition ratio	Change	Percent Change
	(¥ millions)	(%)	(¥ millions)	(%)	(¥ millions)	(%)
Net sales	51,769	100.0	59,883	100.0	+8,114	+15.7
Operating profit	5,743	11.1	8,546	14.3	+2,803	+48.8
Ordinary profit	6,169	11.9	7,665	12.8	+1,495	+24.2
Profit attributable to owners of parent	3,503	6.8	6,545	10.9	+3,042	+86.8
Earnings per share	¥194	1.07	¥377	7.14		

The situation in Ukraine had no significant direct impact on the Group during the period under review.

# Breakdown of Non-operating income and expenses/Extraordinary income and losses/Income taxes/Profit (loss) attributable to non-controlling interests

(¥ millions)	FY2022 Q2	FY2023 Q2
Non-operating income	530	63
Interest income	1	5
Foreign exchange gains	467	-
Subsidy income	13	26
Other	47	30
Non-operating expenses	104	945
Interest expenses	74	94
Foreign exchange losses	_	809
Share of loss of entities accounted for using equity method	_	19
Other	29	22

(¥ millions)	FY2022 Q2	FY2023 Q2
Extraordinary income	_	3,349
Gain on sale of investment securities	-	3,349
Extraordinary losses	51	86
Loss on retirement of non-current assets	43	27
Loss on valuation of investment securities	8	11
Loss on liquidation of subsidiaries	-	47
Income taxes	2,631	4,388
Profit (loss) attributable to non-controlling interests	(17)	(6)

## Sales & Operating profit by reportable segment



		FY2022 Q2 Amount (¥ millions)	FY2023 Q2 Amount (¥ millions)	Change (¥ millions)	Percent change (%)
Pharmaceutical	Sales	36,820	42,309	+5,488	+14.9
Solutions	Operating profit	2,326	3,559	+1,233	+53.0
Healthcare	Sales	15,262	18,443	+3,181	+20.8
Solutions	Operating profit	4,182	5,892	+1,710	+40.9
Adjustes ante	Sales	(314)	(870)	(556)	_
Adjustments	Operating profit	(765)	(905)	(139)	_
Concolidated	Sales	51,769	59,883	+8,114	+15.7
Consolidated	Operating profit	5,743	8,546	+2,803	+48.8

\*Adjustments

Sales are internal elimination of transactions between reporting segments .

Operating profit represents corporate expenses that are not allocated to each reportable segment and are related to the Company (holding company).



	FY2022	Q2	FY2023 Q2				
	Orders received	Backlog	Orders received	Percent Change	Backlog	Percent Change	
	(¥ millions)	(¥ millions)	(¥ millions)	(%)	(¥ millions)	(%)	
Pharmaceutical Solutions	44,327	77,688	40,737	(8.1)	76,772	(1.2)	
Healthcare Solutions	15,334	16,947	19,915	+29.9	17,900	+5.6	
T o t a l	59,661	94,636	60,653	+1.7	94,672	+0.0	

## **Sales composition ratio**







Operating profit	¥2,326million
Operating margin	6.3%

Operating profit	¥3,559million
Operating margin	8.4%

## **Business Segment: CRO Business**

#### Comprehensive support for research and development of disease prevention and treatment

#### **Business Overview**

- Sales increased from the same period of the previous year
- Strengthen comprehensive consulting services for overseas bio ventures entering the Japanese market and other industries entering the healthcare field
- Increase in support for DX (Digital Transformation) promotion and DTx (Digital Therapeutics) entry
- Increase in projects for efficacy and safety evaluation and analysis in cutting-edge areas where modalities are diversifying, such as next-generation antibody drugs, nucleic acid drugs, gene therapeutics, and biomarkers



#### **Focus activities**

 Enhanced development support for advanced therapies such as biologics and regenerative medicine

(full support for filing by Academia and BV)

- Digital applications such as DCT and RWD
- Proactive take on nucleic acid medicine projects via collaboration of laboratories in Japan and the U.S.
- Proactive take on global clinical studies (clinical trials in Asia, Japan-US bioanalysis business)
- Business expansion to the U.S. and Asia
- Aim for the #1 share in Japan

## **Business Segment: CDMO Business**

Development and manufacturing support for pharmaceutical products and biopharmaceutical API from clinical to commercial

### **Business Overview**

- Sales increased from the same period of the previous year
- Growing need to ensure stable supply in response to the spread of COVID-19 and generic quality issues
- Increase in manufacturing costs due to higher prices for energy, raw materials, packaging materials, etc.
- Respond to supply shortage risks, such as prolonged delivery times, in cooperation with customers and suppliers
- Delayed recovery in US performance, focus on acquiring new projects



#### **Focus activities**

- Steady implementation of production at the Ashikaga injectable facility and its contribution to earnings
- Full-scale development of licensing business for formulation technologies (microneedles, etc.)
- Expand business at the new U.S. site
- Strengthen our position as a strategic partner for domestic pharmaceutical companies

## **Business Segment: Market Solutions Business**

Medical, sales and marketing support for pharmaceuticals, and orphan drugs development to commercialization

### **Business Overview**

- Sales increased from the same period of the previous year
- Received many customer inquiries for MR dispatch services
- Commencement of Phase III clinical trials in Japan for glycerol phenylbutyrate (overseas trade name: Ravicti<sup>®</sup>), a treatment for urea cycle disorders, and associated increase in R&D expenses



#### **Focus activities**

- Expand positioning in the MR dispatch business
- Efficient recruitment of MRs and MSLs
- Provision of hybrid services
- Promotion of multi-channel
- Development of new orphan drugs
- Supporting foreign pharmaceutical companies entering the Japanese market



**Operating profit** 

**Operating margin** 

¥5,892million

31.9%

<b>Operating profit</b>	¥4,182million
Operating margin	27.4%

## **Business Segment: Site Support Solutions Business**

Healthcare Solutions

#### Comprehensive support of medical institutes and medical staff

### **Business Overview**

- Sales decreased from the same period of the previous fiscal year due to a decline in large new coronavirus vaccine development projects
- Solid orders received
- Expansion of Clinical Trial Office Support for Medical Institutions
- Expand collaboration with academia



### **Focus activities**

- Shifting from treatment to prevention/prognosis market (prophylaxis treatment agents and clinical trials using apps)
- Providing support for university hospital network, etc.
- Providing services in community healthcare

## **Business Segment: Healthcare Revolution Business**

#### Support individuals, local governments, etc. with solutions using a new ecosystem of health care

### **Business Overview**

- Sales significantly exceeded the same period of the previous year
- Continued support services related to COVID-19
- Expansion of businesses that integrate disease prevention, health information, and IT technologies
  - Increase in the number of medical institutions introducing "nanacara", a support platform for epilepsy patients and their families, and expansion of target diseases for nanacara-based services
  - Support for local government projects in line with the "Digital Garden Cities and Green Transformation"



#### **Focus activities**

- Expansion of healthcare services & utilization of data by using harmo<sup>®</sup>
- Expansion of healthcare services for local governments and companies



- Expansion of self-screening services
- Nurture and secure healthcare human resources

## **Consolidated balance sheet (assets)**





2023/3

## **Consolidated balance sheet (liabilities and net assets)**



## **Cash Flows**



(¥ millions)	2022/3	2023/3	Increase (decrease)
Cash flows from operating activities	4,011	2,168	(1,842)
Cash flows from investing activities	(3,682)	267	+3,950
Cash flows from financing activities	906	(114)	(1,020)
Effect of exchange rate change on cash and cash equivalents	(278)	(40)	+237
Net increase(decrease) in cash and cash equivalents	956	2,281	+1,325
Increase in cash and cash equivalents resulting from inclusion of subsidiaries in consolidation	60	_	(60)
Cash and cash equivalents at beginning of period	9,379	11,703	+2,323
Cash and cash equivalents at end of period	10,395	13,984	+3,588

(Cash flow from operating activities)

[Key factors]

• Increase in funds due to recording of profit before income taxes, decrease in funds due to payment of income taxes and bonus payments, etc.

#### (Cash flow from investing activities)

• Increase in funds from sale of investment securities, decrease in funds from acquisition of fixed assets, etc.

(Cash flow from financing activities)

• Increase in funds due to long-term borrowings, decrease in funds due to cash dividends paid and purchase of treasury shares, etc.



# **Forecast for FY ending Sep. 2023**





	2022/9 Actual (¥ millions)	2023/9 Plan (¥ millions)	2023/9 Forecast (¥ millions)	(¥ Change from the original plan (%)	millions) 15,000			11,845		10 200		- 20% - 15%
Net Sales	108,461	95,000	105,000	+10.5	10,000 -					10,300		1370
Operating profit	11,845	5,000	10,300	+106.0	-			10.9%		9.8%	-	- 10%
Ordinary profit	13,450	4,700	9,000	+91.5	5,000 -	<b>4,920</b> 5.7%						- 5%
Profit attributable to owners of parent	8,387	2,900	7,300	+151.7	0 -							- 0%
Earnings per share	¥ 469.44	¥ 165.23	¥ 420.42			2021/9 Operatir	ng profit	2022/9 t <b></b> 0	perating	2023/9E margin	I	0 /0

# CMIC CMO becomes an equity-method affiliate and forms a strategic business alliance with Dai Nippon Printing (DNP)

Division Director of CDMO Business Makoto Matsukawa



### **Reason for Partnership**

- ✓ CMIC Group to maintain its strategic policy of developing PVC models and expand and grow CMIC CMO
- ✓ Effective utilization of group resources to create healthcare business and achieve sustainable growth

### **Details of Cooperation**

- (1) Development of value-added pharmaceutical products by combining the packaging technology of the DNP Group with the formulation development technology of the CMIC Group
- (2) Establishment of an end-to-end system from process development and manufacturing of active pharmaceutical ingredients by the DNP Group to formulation development and manufacturing by the CMIC
- (3) Collaboration in the CMIC Group's clinical development and clinical trial site support business, utilizing the DNP Group's technology and know-how
- (4) Business Alliance to Build a Healthcare Ecosystem

## Joint initiatives with DNP in CDMO business



The joint venture will maintain CMIC CMO's previous management structure and organization, while leveraging DNP's expertise in contract manufacturing in other businesses.

- CMIC CMO's formulation technology and DNP's packaging technology will be combined to develop value-added formulations that are user-friendly and consider not only production costs but also the environment.
  - Currently developing a product using deoxygenated packaging technology that enables liquid formulation of freeze-dried injectable products that remains stable at room temperature
  - Promoting practical application of drug manufacturing utilizing 3D printing technology (in collaboration with Apricia)
- ✓ Collaboration between DNP's API business unit and CMIC CMO to nurture an integrated business from API to drug product development and manufacturing
- ✓ Application of DNP's production automation system to drug manufacturing





### 1

Providing one-stop service for pharmaceutical manufacturing

- Provide comprehensive supply chain solutions: from API to formulation
- Design and evaluation of API properties suitable for formulation development and manufacturing
- Packaging design services

#### 2

#### **Competitive API supply**

- Procurement of raw materials and intermediates from reliable channels at low prices
- Stable supply of domestic brand high quality API
- Efficient and highly productive operation utilizing compact sites/facilities

## **DNP** alliance model to develop & manufacture GE new products



In the development of new GE products, we have concluded joint development and manufacturing consignment agreements with multiple GE manufacturers, and have CMIC/DNP handle everything from API to development and manufacturing, with the aim of improving operational efficiency and reducing costs through formation of an ecosystem (platform)



\*As an alternative, consider OEM models for GE products using CMIC Group's manufacturing and marketing capabilities



1	Name	CMIC CMO Co., Ltd
2	Address	1-1-1 Shibaura, Minato-ku, Tokyo
3	Title and name of representative	Toshiki Sugimoto, Chairman and Representative Director (DNP) Makoto Matsukawa, CEO and Representative Director
4	Business	Manufacture, import, export and sales of pharmaceutical products
5	Capital	100 million yen
6	Shareholders	CMIC Holdings 49.9%, Dai Nippon Printing 50.1%



# Future expansion - Our challenge towards maximizing personal health value -

CMIC Group CEO Dr. Kazuo Nakamura



## **Healthcare Revolution – CMIC's Philosophy**



conventional medicine, disease prevention, and MIBYO (presymptomatic medicine)

and continue to contribute to society and humanity.



To let everyone live their once and only life to its fullest, it is important not only to devote our efforts in disease treatment, but also to hold the perspective of IKIGAI: Happiness of each and every person. Such spirit is embodied in CMIC's CREED, which is at the core of our innovation to bring about new healthcare value.







# **Healthcare Revolution**



## **Healthcare Revolution**



Aiming to create businesses that contribute to the maintenance and promotion of personal health and to create a new platform

#### Healthcare Revolution2.0 (from 2021)

- Response to the changing environment due to COVID-19
- Providing individuals and municipalities with new ecosystem solutions

### Healthcare Revolution1.0 (from 2019)

- ► Realization of CMIC CREED
- Establishment of In-House Healthcare Professional System and Talent Development
- Transformation from Pharma Model to Innovative Healthcare Pharma Model


# Healthcare Revolution 2.0 Response to the changing environment due to COVID-19

- Demonstrating the Value of Healthcare Talents in Support of Municipalities -



### The COVID Vaccine Changed the Value Chain/Supply Chain





#### **CMIC's New Role in the COVID-era**



#### Mass vaccination venue



#### **PCR caravan**



#### Vaccine bus

Vaccination made possible on "Vaccine buses" in Tokyo, Japan

Vaccination completed on 45 users and staffs within 1 hour

#### Vaccination caravan for medical institutions



### [harmo utilization]



### Local government support based on "IKIGAI"

### Comprehensive support for infection control and personal health control



### We also provide a variety of other services to meet needs.

### **Healthcare Revolution**



Aiming to create businesses that contribute to the maintenance and promotion of personal health and to create a new platform

From April 2023

Healthcare Revolution 3.0 Toward the realization of PHVC

From 2020

Healthcare Revolution 2.0

From 2019

Healthcare Revolution **1.0** 

#### **PHVC: Personal Healthcare Value Creator**



# Healthcare Revolution 3.0 towards the realization as Personal Healthcare Value Creators





### Seizure Recording App Born from the Voices of Patient Families and Epileptologists

Smartphone app that allows children with epilepsy and their families to manage and share daily information such as medication status and seizure frequency with family members and doctors





Aiming to provide a wide range of patient-centered services by expanding services based on nanacara to other therapeutic areas

### **Operate a platform with high app usage**



# The monthly usage rate of the app (nanacara) by patients' families is as high as approximately 60%.



System to solve the gap between patients and doctors when treating epilepsy Quickly communicate correct seizure records to physicians and other health care professionals



Patients with epilepsy: 1 million Patients with intractable epilepsy: 300,000(including 100,000 children)

Pediatric epilepsy use: approx. 25,000 institutions: 450 Medical institutions: approx. 200

**Epileptologists:** 

700Number of medical

Enrollment of patients with intractable epilepsy symptoms and many rare diseases

Seizure and medication data can be analyzed and reported

# Rare diseases 20%

#### Disease/Symptom Segment

- •West syndrome
- Dravet syndrome
- •Lennox syndrome
- Rett syndrome
- Tuberous sclerosis complex
- •Ohtahara syndrome
- •CDKL5 deficiency disorder
- Aicardi syndrome
- MECP2 duplication syndrome
- Angelman syndrome
- Fukuyama congenital muscular dystrophy etc.

### Examples of Recorded Data

- Medications
- Prescription trends
- Seizure frequency
- Number of seizures
- •Seizure onset time
- Seizure duration
- •Age
- Gender
- Place of residence
- · Family medical institution
- Family doctor



# 💦 nana-**medi**

### **Online medical consultation and pharmacy app**

Able to connect with a doctor or pharmacist from home or work via a smartphone and receive medical consultation and medication guidance.

It is estimated that there are approximately 1 million epilepsy patients in Japan, but specialists are concentrated in urban areas and there is a large regional bias. The use of digital devices is expected to improve regional disparities in epilepsy treatment.



#### Our app is the de facto standard for pediatric epilepsy treatment apps



# Apps distributed to medical institutions mainly through referrals from patients' families. Used by about half of Epileptologists.





# **PHR** Personal Health Record





#### **Personal Health Record**

A system in which individuals collect their own medical, health, and nursing care information using digital technology and store it centrally. The data can then be provided to medical institutions and used for other purposes.

Governments, municipalities, and private companies are focusing on the use of PHRs to improve individual health and lifestyle



#### **Electronic Medication Notebook Guidelines Revised Significantly for the First Time in Eight Years**



The rules to be followed by e-medicine notebook providers and medical institutions that have introduced the e-medicine notebook, "Operational considerations for the e-medicine notebook," have been overridden as the "Guidelines for the e-medicine notebook," the first major revision in about eight years

ールとして活用されることが期待される。また、他の PHR サービスとの連携等により、
体重等の各種健康情報と併せて健康づくりの支援ツールとして活用されること、オンライン服薬指導やオンライン診療のサービスなど関連したサービスと連携することが期待される。現状では紙のお薬手帳の利用者が多いが、今後は、すべての薬局、診療所、病院で電子版お薬手帳サービスの活用を推進することが望まれる。各提供薬局・診療所・病院(以下「提供施設」という。)等において、電子版お薬手帳の意義・役割や活用方法を広く周知するとともに、利用を推奨することが求められる。

It clearly states that "all pharmacies, clinics, and hospitals should promote the use of the electronic version of the Medication Record Book service."

Important points

- 1. Promotion of electronic rather than paper. Medical institutions were encouraged to use the service
- 2. Electronic versions of the medicine notebook were clearly positioned as part of PHRs.
- 3. Secondary use of the e-medicine notebook is now subject to the same standards as PHRs.
- 4. Functional requirements for the e-medicine notebook were clearly defined.

保健所設置市 薬務主管部(局) 厚生労働省医薬·生活衛生局総務課長 (公 印 省 電子版お薬手帳ガイドラインについて 医薬行政の推進につきましては、平素から格別の御高配を賜り げます。 電子版お薬手帳については、「お薬手帳(電子版)の運用上の留意事項について」 留意事項通知」という。)により、利用者にお薬手帳サ 機関や、アプリケーションの提供やデータ保存を行う運営事業者向けに、 留意事項をお示ししてきたところです。 厚生労働省委託事業「データヘルス改革を見据えた次世代型お を通じて、オンライン資格確認の普及、電子処方箋の運用開 元的な管理の重要性を整理し、先の留意事項通知を踏まえつつ、 版お薬手帳ガイドライン」を作成いたしました。本ガイドライン 事業者において対応が必要と考えられる事項や、電子 ービスを提供する施設における留意事項をまとめており、本通知の発出に伴い、留意 事項通知は廃止いたします。 ましては、貴管内の薬局、医療機関等の関係団体等に対し、本ガイドライン の周知をいただきますよう、よろしくお願いいたします。 本ガイドラインにおいては、「実装すべき機能」、「実装が望ましい機能」 「将来的に実装が望ましい機能」として、電子版お薬手帳に求められる機能を体系的 に整理しています。「実装すべき機能」については、本通知の発出から1年を目処と して実装いただくよう運営事業者に依頼しておりますので、その旨申し添えます。



Establishing a system that integrates the various information required for infant health checkups and vaccinations using a distribution platform based on <u>blockchain technology</u>, and shares and utilizes it <u>in real time</u> among medical institutions and payers <u>through ID</u> <u>linkage</u> with the My Number system.





# **CMIC's Goals**

# From CRO to PVC and PHVC





### PHVC

Personal Health Value Creator

A group of professionals who can further develop PVC and contribute to the healthcare needs of individuals

**PVC** 

Pharmaceutical Value Creator A group of professionals who can contribute to the evolution of the pharmaceutical industry

### CRO

Contract Research Organization

A group skilled in drug development



Pharmaceutical Value Creator

A group of professionals who can contribute to the evolution of the pharmaceutical industry

# Thank you for your attention.





Cautionary statement:

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