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April 28, 2021

CMIC HOLDINGS Co., Ltd. Consolidated Financial Results For the 2nd Quarter Ended March 31, 2021

(The Fiscal Year Ending September 30, 2021, Japan Accounting Standards)

Highlights:

- ◆ **Sales decreased 0.8% year on year to ¥38.645 billion on a consolidated basis**
- ◆ **Operating income increased 9.5% to ¥2,158 million**
- ◆ **Earnings per share: ¥67.58**
- ◆ **Order backlog of contract services grew 8.5% year on year**

Tokyo, April 28, 2021 – CMIC HOLDINGS Co., Ltd. (TSE Code: 2309) today reported financial results for the 2nd quarter ended March 31, 2021.

CMIC Group is rolling out a PVC (Pharmaceutical Value Creator) model, which is our unique business model contributing to increasing additional values of pharmaceutical companies. We provide extensive support for development, manufacturing, sales and marketing value chains of pharmaceutical companies with our CRO (Contract Research Organization) business, CDMO (Contract Development Manufacturing Organization) business, CSO (Contract Sales Organization) business, and Healthcare business. In addition, our IPM (Innovative Pharma Model) business is providing new business solutions to pharmaceutical companies that combine marketing authorization licenses (intellectual properties) and value chains.

In the pharmaceutical industry, while the creation of innovative drugs is expected through technological innovation and industry-government-academia collaboration towards providing personalized medicine or “precision medicine,” NHI price revisions are implemented on an annual basis starting in FY2021. In the first mid-year revision, a large number of drugs were subject to NHI price reductions, which has put pressure on the earnings of pharmaceutical companies. In response, pharmaceutical companies are expanding their development pipelines through M&A and other means, strengthening their overseas operations, and improving management efficiency.

Furthermore, in R&D, the development of pharmaceuticals using new basic drug discovery technologies, efforts to provide total care for diseases ranging from prevention to diagnosis to treatment to prognosis, and research and development using new technologies such as artificial intelligence (AI) and IoT are being accelerated. On the other hand, since the last year, there have been a series of voluntary recalls by generic drug manufacturers and cases of production using non-approved manufacturing methods have been uncovered. Here once again, the quality of pharmaceutical products is being required to be strictly controlled.

While local governments are preparing for vaccination as a countermeasure against COVID-19 infection, with no end in sight to the spread of the infection with multiple variants emerging, clinical trial implementation and safety information collection in remote environments, real-world data utilization, and other means are expected to further

promote the speed and efficiency of drug development.

CMIC Group is executing the focus activities in the mid-term business plan (FY2019-2021) to adapt ourselves to the rapidly changing external environment. While promoting various measures, including 1) Acceleration of PVC model, 2) Promoting globalization, and 3) Creation of healthcare business, we have started the “Healthcare Revolution” project to transform ourselves from a business model centering on pharmaceutical drugs to the creation of new healthcare business. We are now creating new businesses that will contribute to maintaining and improving personal health, and utilizing our talents in the healthcare arena.

CMIC Group will support the development of effective treatment and preventive measures against the COVID-19 infection, contribute to providing efficacious treatment for early recovery of patients and maintaining the medical system, and deliver our mission as a healthcare company.

Sales and Operating Income

In the consolidated cumulative second quarter, we focused on sales activities to win new projects such as those of developmental and post-marketing support services for COVID-19 infection treatment drugs, while addressing the top-priority items identified in the mid-term plan, including new support services for local governments for their countermeasures against COVID-19 infection. Due to the spread of COVID-19 infection, we are still self-imposing restrictions on visits to medical institutions and facing delays in the progress of some developmental projects, while remote-based business activities have taken root and inquiries are increasing.

Sales in the consolidated cumulative second quarter was ¥38.645 billion (down 0.8% year-on-year), which was at the same level as the same period of the previous year. Operating income was 2,158 million (up 9.5% year-on-year), which was above the same period of the previous year, due to factors such as an increase in the CDMO business.

Segment Information

The business results by segment are listed as below:

● CRO (Contract Research Organization) Business

	(Millions of yen)			
	1H FY2021	1H FY2020	YoY Change Amount	YoY Change %
Sales	17,567	17,898	(331)	(1.9)
Operating income	2,813	2,930	(117)	(4.0)

In this business, we provide services primarily to pharmaceutical companies to support drug development.

In the consolidated cumulative second quarter, we supported overseas companies entering the Japanese market and non-healthcare companies entering the healthcare sphere and promoted measures to address increasingly sophisticated development needs, including biopharmaceuticals and regenerative medicines, while helping to maximize the speed of drug development by offering one-stop service from non-clinical to post-marketing. For clinical services, we are working to improve the efficiency of clinical trial process by using the healthcare

communication channel *harmo*®, proposing a new clinical trial model in the age of New Normal, and improving the expertise and technical capabilities of our talents.

For non-clinical services, our laboratories in Japan and the United States are in collaboration to actively provide drug discovery support for advanced medicine, including nucleic acid drugs and regenerative medicines.

Sales were below the same period of the previous year due to factors such as the weakness in orders for clinical operations in the previous consolidated fiscal year as a result of the spread of COVID-19 infection. Operating income was below the same period of the previous year due to factors such as a decrease in revenue from clinical operations, despite an increase in non-clinical operations.

- **CDMO (Contract Development Manufacturing Organization) Business**

	(Millions of yen)			
	1H2FY2021	1H FY2020	YoY Change Amount	YoY Change %
Sales	10,505	10,325	+179	+1.7
Operating income	270	147	+122	+83.5

In this business, we provide services primarily to pharmaceutical companies to support drug formulation development and manufacturing.

In the consolidated cumulative second quarter, CDMO business is further improving technical capabilities and quality, developing a low-cost production structure, and enhancing competitiveness through strategic capital investment as a global pharmaceutical drug manufacturing platform that includes formulation design, investigational new drug manufacturing, and commercial production. We are focusing on a large-scale commercial production project that is scheduled to start production in the fiscal year ending September 30, 2022, the launch of new facility and production line in the United States, and the acquisition of new projects. Sales were above the same period of the previous year due to factors such as an increase in contracted production volume. Operating income was above the same period of the previous year due to the increase in sales, despite prior investment costs for the contract manufacturing business of biopharmaceutical APIs.

- **CSO (Contract Sales Organization) Business**

	(Millions of yen)			
	1H FY2021	1H FY2020	YoY Change Amount	YoY Change %
Sales	4,190	4,313	(122)	(2.8)
Operating income	435	437	(2)	(0.6)

In this business, we provide sales- and marketing-support services, primarily to pharmaceutical companies.

In the consolidated cumulative second quarter, in addition to the medical representative (MR) dispatch and other related new services, we are strengthening the sales activities for Medical Affairs-related operations and providing comprehensive solution that combines multiple communication channels and various services.

Sales and operating income were at the same level as the same period of the previous year, despite a slight decline in the operation rate in the MR dispatch services.

- **Healthcare Business**

	(Millions of yen)			
	1H FY2021	1H FY2020	YoY Change Amount	YoY Change %
Sales	5,300	4,892	+408	+8.3
Operating income	341	262	+78	+29.9

In this business, we provide SMO (Site Management Organization) services, as well as healthcare services related to treating and maintaining and promoting the health mainly for medical institutions, patients, and general consumers.

In the consolidated cumulative second quarter, we are focusing on supporting the development of effective treatment and preventive measures against COVID-19 infection, as well as supporting the setup of PCR testing and vaccination systems by local governments. We will continue to work on the healthcare communication channel *harmo@* business and create new healthcare business that contributes to the early detection of disease and prevention of disease aggravation, while winning new SMO business orders and aiming to expedite the in-flow of income for the new healthcare business.

Sales were above the same period of the previous year due to growth in the SMO operations, etc. Operating income was also above the same period of the previous year due to an increase in sales, despite prior investments for the creation of new healthcare business.

- **IPM (Innovative Pharma Model) Business**

	(Millions of yen)			
	1H FY2021	1H FY2020	YoY Change Amount	YoY Change %
Sales	1,473	1,912	(439)	(23.0)
Operating income	63	67	(4)	(6.2)

IPM business provides new business solutions to pharmaceutical companies that combine value chains and marketing authorization licenses (intellectual properties) possessed by our Group. We are mainly delivering development and marketing services for orphan drugs and diagnostics.

In addition to selling orphan drugs, etc., including products developed in-house, we are strengthening our business foundation through the provision of IPM platform that includes supporting foreign pharmaceutical companies entering the Japanese market and providing strategic options to pharmaceutical companies following changes in their business models. Multiple projects are progressing with increased demand in recent years from

foreign pharmaceutical companies to use our IPM platform. In January 2021, we received a manufacturing and marketing approval in Japan of *ORLADEYO Capsules 150mg* for the suppression of the onset of attacks in acute hereditary angioedema (HAE). At the same time, *Lynspad™ for Intravenous Infusion 1000 mg* of Grifols Therapeutics LLC received a manufacturing and marketing approval in Japan, in which we have provided support toward the approval as an appointed marketing authorization holder and are expected to support its marketing. We will further expand our business scale and secure profitability by continuing to provide new business solutions.

Sales were below the same period of the previous year due to a decrease in sales volumes of some products. On the other hand, operating income was at the same level as the same period of the previous year due to effects such as the one from reduction in cost.

Ordinary Income

Ordinary income in the consolidated cumulative second quarter was ¥2,368 million (down 0.0% year-on-year).

For non-operating income, we recorded ¥326 million of foreign exchange gains, subsidy income, and others, and for non-operating expenses, we recorded ¥116 million of interest expenses and others.

Profit attributable to owners of parent

Profit attributable to owners of parent in the consolidated cumulative second quarter was ¥1,222 million (down 17.4% year-on-year).

We recorded ¥116 million as gain on forgiveness of debts for extraordinary income, ¥58 million as loss on retirement of non-current assets and loss on valuation of investment securities for extraordinary loss, ¥1,004 million for total income taxes, and ¥199 million as profit attributable to non-controlling interests.

Overview of the financial condition

Assets, liabilities, and net assets

Total assets at the end of the consolidated cumulative second quarter increased by ¥2,484 million compared with the end of the previous consolidated fiscal year to ¥92,002 million. This is due mainly to an increase in notes and accounts receivable-trade, tangible non-current assets in the CDMO business, and others and a decrease in cash and deposits and others.

Total liabilities increased by ¥1,053 million compared with the end of the previous consolidated fiscal year to ¥56,559 million. This is due mainly to an increase in “other” of the current liabilities and long-term debt and a decrease in short-term borrowings, commercial papers, and others.

Total net assets increased by ¥1,431 million compared with the end of the previous consolidated fiscal year to ¥35,442 million. This is due mainly to an increase in retained earnings.

Future Outlook

The impacts associated with the spread of COVID-19 infection on our business are anticipated to include delays in collecting data and others due to restrictions on visits to medical institutions and a decrease in contracted production volume due to decreased sales of pharmaceuticals as a result of the priority

measures to prevent the spread of disease and the state of emergency. In the meantime, we will strive to enhance order-taking activities for clinical trials and post-marketing surveillance projects related to the COVID-19 infection and expand support services for vaccination activities by local governments.

While there is no clear end in sight to the spread of COVID-19 infection, based on the information available at this point in time, there are no changes to the consolidated earnings forecast for the fiscal year ended September 30, 2021 in the "Consolidated Financial Results for the Fiscal Year Ended September 30, 2020" announced on November 6, 2020.

If there is expected to be an impact on our business performance in the future, we will disclose it promptly.

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.

Summary of Results for the 2nd Quarter Ended March 31, 2021 (October 1, 2020 through March 31, 2021)

(1) Consolidated financial results (Millions of yen; amounts less than one million yen are omitted)
 (Percentage figures indicate increase/decrease compared with the corresponding period of the prior fiscal year)

	1H FY2021		1H FY2020	
		Change (%)		Change (%)
Net sales	38,645	(0.8)	38,958	6.3
Operating income	2,158	9.5	1,970	(31.6)
Ordinary income	2,368	(0.0)	2,368	(11.0)
Profit attributable to owners of parent	1,222	(17.4)	1,479	(3.7)
Earnings per share (Yen)	67.58		81.86	
Diluted net income per share (Yen)	—		—	

Reference: Comprehensive income: 1st half FY2021: ¥1,815 million (up 34.3% YoY)

1st half FY2020: ¥1,351 million (up 72.6% YoY)

(2) Consolidated financial position (Millions of yen; amounts less than one million yen are omitted)

	End Q2 FY2021	Year End FY2020
Total assets	92,002	89,517
Net assets	35,442	34,011
Equity ratio (%)	27.0	26.4
Book value per share (Yen)	1,373.70	1,306.08

Reference: Shareholders' equity: 2nd quarter FY2021: ¥24,850 million

Year End FY2020: ¥23,627 million

Distribution Status

	(Yen)		
	FY2020	FY2021	FY2021 (Estimated)
Dividend per share (Base date)			
End of first quarter	—	—	—
End of second quarter	5.00	5.00	—
End of third quarter	—		—
End of FY	20.00		22.00
Total	25.00		27.00

We regard the return of profits to shareholders as one of our most important management policies. Our basic policy is to pay dividends in accordance with our business performance, while securing internal reserves to improve profitability and strengthen our business foundation. At the same time, we will maintain a consolidated dividend payout ratio of 30% and pay continuous and stable dividends. For the time being, the minimum annual dividend is set at ¥10.00 for stable dividends.

Consolidated Financial Statements for the 2nd Quarter Ended March 31, 2021

(1) Consolidated Balance Sheets

(Millions of yen)

	Q2 FY2021 (March 31, 2021)	Year End FY2020 (September 30, 2020)
Assets		
Current assets		
Cash and deposits	10,591	12,690
Notes and accounts receivable – trade	14,835	13,211
Merchandise and finished goods	860	729
Work in process	4,035	3,985
Raw materials and supplies	3,307	3,196
Other	4,380	3,696
Allowance for doubtful accounts	(58)	(66)
Total current assets	37,951	37,443
Non-current assets		
Property, plant and equipment		
Buildings and structures, net	14,982	15,221
Machinery, equipment and vehicles, net	11,772	12,008
Land	6,464	6,425
Other, net	8,989	6,603
Total property, plant and equipment	42,208	40,258
Intangible assets		
Goodwill	65	76
Other	1,777	1,645
Total intangible assets	1,842	1,721
Investments and other assets		
Investment securities	3,997	3,962
Lease and guarantee deposits	1,966	1,971
Other	4,632	4,727
Allowance for doubtful accounts	(597)	(567)
Total investments and other assets	9,998	10,093
Total non-current assets	54,050	52,074
Total assets	92,002	89,517

(Millions of yen)

	Q2 FY2021 (March 31, 2020)	Year End FY2020 (September 30, 2020)
Liabilities		
Current liabilities		
Notes and accounts payable – trade	846	1,019
Short-term borrowings	1,918	6,004
Current portion of long-term debt	3,539	3,258
Commercial papers	2,000	3,000
Income taxes payable	1,302	586
Provision for bonuses	2,183	2,413
Provision for loss on orders received	902	824
Other	13,674	12,084
Total current liabilities	26,365	29,191
Non-current liabilities		
Long-term debt	14,211	10,321
Net defined benefit liability	10,100	9,931
Other	5,882	6,061
Total non-current liabilities	30,193	26,314
Total liabilities	56,559	55,506
Net assets		
Shareholders' equity		
Capital stock	3,087	3,087
Capital surplus	6,100	6,100
Retained earnings	15,890	15,052
Treasury shares	(1,545)	(1,545)
Total shareholders' equity	23,532	22,694
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	1,365	1,336
Foreign currency translation adjustments	11	(29)
Remeasurements of defined benefit plans	(59)	(373)
Total accumulated other comprehensive income	1,317	933
Non-controlling interests	10,592	10,384
Total net assets	35,442	34,011
Total liabilities and net assets	92,002	89,517

(2) Consolidated Statement of Income

(Millions of yen)

	1H Y2021 (October 1, 2020– March 31, 2021	1H Y2020 (October 1, 2019– March 31, 2020
Net sales	38,645	38,958
Cost of sales	30,333	30,782
Gross profit	8,312	8,176
Selling, general and administrative expenses	6,153	6,205
Operating income	2,158	1,970
Non-operating income		
Interest income	1	2
Foreign exchange gains	159	-
Share of profit of entities accounted for using equity method	20	421
Subsidy income	91	9
Other	53	59
Total non-operating income	326	492
Non-operating expenses		
Interest expenses	64	57
Foreign exchange losses	-	13
Provision of allowance for doubtful accounts	27	-
Other	25	23
Total non-operating expenses	116	94
Ordinary income	2,368	2,368
Extraordinary income		
Gain on sales of non-current assets	-	5
Gain on forgiveness of debts	116	-
Total extraordinary income	116	5
Extraordinary losses		
Loss on retirement of non-current assets	25	47
Loss on valuation of investment securities	32	66
Total extraordinary losses	58	114
Profit before income taxes	2,426	2,259
Total income taxes	1,004	674
Profit	1,421	1,585
Profit attributable to non-controlling interests	199	105
Profit attributable to owners of parent	1,222	1,479

(3) Consolidated Statement of Comprehensive Income

(Millions of yen)

	1H FY2021 (October 1, 2020– March 31, 2021)	1H FY2020 (October 1, 2019– March 31, 2020)
Profit	1,421	1,585
Other comprehensive income		
Valuation difference on available-for-sale securities	29	(254)
Foreign currency translation adjustments	39	(16)
Remeasurements of defined benefit plans	323	38
Share of other comprehensive income of entities accounted for using equity method	0	-
Total other comprehensive income	393	(233)
Comprehensive income	1,815	1,351
Comprehensive income attributable to		
Owners of parent	1,607	1,223
Non-controlling interests	207	127

(4) Consolidated Statement of Cash Flows

(Millions of yen)

	1H FY2021 (October 1, 2020– March 31, 2021)	1H FY2020 (October 1, 2019 March 31, 2020)
Cash flows from operating activities:		
Profit before income taxes	2,426	2,259
Depreciation	2,508	1,993
Amortization of goodwill	10	148
Increase (decrease) in allowance for doubtful accounts	18	(7)
Interest and dividend income	(1)	(2)
Interest expenses	64	57
Foreign exchange losses (gains)	(27)	7
Share of loss (profit) of entities accounted for using equity method	(20)	(421)
Decrease (increase) in notes and accounts receivable -trade	(1,567)	(555)
Decrease (increase) in inventories	(274)	73
Increase (decrease) in notes and accounts payable - trade	(186)	(164)
Increase (decrease) in provision for bonuses	(234)	(605)
Increase (decrease) in net defined benefit liability	636	398
Loss (gain) on valuation of investment securities	32	66
Loss on retirement of non-current assets	25	47
Gain on forgiveness of debt	(116)	-
Subsidy income	(91)	(9)
Increase (decrease) in advances received	491	221
Increase (decrease) in accrued expenses	(177)	(131)
Other, net	(976)	(794)
Subtotal	2,542	2,581
Interest and dividend income received	46	2
Interest expenses paid	(75)	(56)
Income taxes paid	(510)	(960)
Proceeds from subsidy income	86	7
Net cash provided by (used in) operating activities	2,089	1,574

Cash flows from investing activities		
Purchase of property, plant and equipment	(2,280)	(2,244)
Purchase of investment securities	(50)	(3)
Purchase of intangible assets	(429)	(203)
Net decrease (increase) in short-term loans receivable	1	(90)
Payments for lease and guarantee deposits	(28)	(361)
Proceeds from collection of lease and guarantee	40	385
Other	16	(2)
Net cash provided by (used in) investing activities	(2,730)	(2,519)
Cash flows from financing activities		
Net increase (decrease) in short-term loans	(4,000)	900
Proceeds from long-term loans payable	5,800	2,250
Repayments of long-term loans payable	(1,629)	(1,420)
Cash dividends paid	(365)	(490)
Repayments of lease obligations	(218)	(82)
Net increase (decrease) in commercial papers	(1,000)	2,000
Other	(0)	(0)
Net cash provided by (used in) financing activities	(1,412)	3,156
Effect of exchange rate change on cash and cash equivalents	(47)	(8)
Net increase (decrease) in cash and cash equivalents	(2,100)	2,202
Cash and cash equivalents at beginning of period	12,688	12,144
Increase in cash and cash equivalents resulting from inclusion of subsidiaries in consolidation	1	-
Decrease in cash and cash equivalents resulting from exclusion of subsidiaries from consolidation	-	(14)
Cash and cash equivalents at end of period	10,589	14,332