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July 30, 2021

CMIC HOLDINGS Co., Ltd. Consolidated Financial Results

For the 3rd Quarter Ended June 30, 2021

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

Highlights:

- ◆ **Sales increased 4.2% year on year to ¥59,146 million on a consolidated basis**
- ◆ **Operating income increased 13.8% to ¥3,571 million**
- ◆ **Earnings per share: ¥107.44**
- ◆ **Order backlog of contract services grew 18.0% year on year**

Tokyo, July 30, 2021 – CMIC HOLDINGS Co., Ltd. (TSE Code: 2309) today reported financial results for the 3rd quarter ended June 30, 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 administering 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. Following such advancement of digitalization, there are some movements to break away from the existing business model.

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 third 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 utilization of CMIC Group talents in the healthcare arena and providing support services for local governments in their fight against COVID-19 pandemic. 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 third quarter was ¥59,146million (up 4.2% year-on-year), operating income was 3,571 million (up 13.8% year-on-year), which both exceeded the same period of the previous year, mainly thanks to the growth of healthcare business.

Segment Information

The business results by segment are listed as below:

- **CRO (Contract Research Organization) Business**

	(Millions of yen)			
	Q3 FY2021	Q3 FY2020	YoY Change Amount	YoY Change %
Sales	25,777	25,605	+172	+0.7
Operating income	3,872	4,288	(416)	(9.7)

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

In the consolidated cumulative third 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 the 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 exceeded the same period of the previous year thanks to the growth of non-clinical business, despite 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.

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

(Millions of yen)

	Q3 FY2021	Q3 FY2020	YoY Change Amount	YoY Change %
Sales	15,617	15,199	+418	+2.8
Operating income	163	15	+148	+946.6

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

In the consolidated cumulative third 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)			
	Q3 FY2021	Q3 FY2020	YoY Change Amount	YoY Change %
Sales	6,600	6,516	+83	+1.3
Operating income	788	768	+20	+2.7

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

In the consolidated cumulative third 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 exceeded the same period of the previous year, thanks to the acquisition of new MR dispatch service projects.

- **Healthcare Business**

	(Millions of yen)			
	Q3 FY2021	Q3 FY2020	YoY Change Amount	YoY Change %
Sales	9,323	7,463	+1,859	+24.9
Operating income	1,142	586	+556	+94.9

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 third quarter, we are focusing on supporting the development of effective treatment and preventive measures against COVID-19 infection, as well as supporting the PCR testing and vaccination 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 significantly above the same period of the previous year due to growth in the BPO and personnel services for vaccination support and SMO operations. Operating income was also significantly 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)			
	Q3 FY2021	Q3 FY2020	YoY Change Amount	YoY Change %
Sales	2,453	2,564	(110)	(4.3)
Operating income	152	121	+30	+25.2

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. Operating income, on the other hand, exceeded the same period of the previous year thanks to cost reduction and other factors.

Ordinary Income

Ordinary income in the consolidated cumulative third quarter was ¥3,733 million (up 7.1% year-on-year).

For non-operating income, we recorded ¥329 million of foreign exchange gains, subsidy income, and others, and for non-operating expenses, we recorded ¥166 million of interest expenses and others.

Profit attributable to owners of parent

Profit attributable to owners of parent in the consolidated cumulative third quarter was ¥1,943million (down 18.1% year-on-year).

We recorded ¥136 million as gain on forgiveness of debts and gain on sales of shares of subsidiaries and associates for extraordinary income, ¥95 million as loss on retirement of non-current assets and loss on valuation of investment securities for extraordinary losses, ¥1,626 million for total income taxes, and ¥203 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 third quarter increased by ¥3,589million compared with the end of the previous consolidated fiscal year to ¥93,107million. 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 ¥1,382 million compared with the end of the previous consolidated fiscal year to ¥56,888 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 and provision for bonuses.

Total net assets increased by ¥2,207 million compared with the end of the previous consolidated fiscal year to ¥36,218 million. This is due mainly to an increase in retained earnings.

Future Outlook

Sales in the fiscal year ending in September 2021 is expected be ¥82,000 million, operating income is expected to be ¥3,500 million, ordinary income is expected to be ¥3,600 million, and profit attributable to owners of parent is expected to be ¥1,700 million.

As a result of the semi-state of emergency and state of emergency coronavirus measures, while there is delay in data collection or decline in contract production volume following the reduced pharmaceutical drug sales volume, we expect to see the growth of vaccination support operations for municipalities.

	Sales	Operating income	Ordinary income	Profit attributable to owners of parent	Earnings per share
	Millions of yen	Millions of yen	Millions of yen	Millions of yen	yen
Original forecast (Announced November 6, 2020) (A)	80,000	3,300	3,100	1,650	91.21
New revised forecast (B)	82,000	3,500	3,600	1,700	93.97
Increase (B-A)	2,000	200	500	50	-
Rate of change (%)	2.5	6.1	16.1	3.0	-
(Reference) Results for the previous fiscal year (FY2020)	76,098	2,605	2,867	1,505	83.27

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 3rd Quarter Ended June 30, 2021 (October 1, 2020 through June 30, 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)

	3Q FY2021		3Q FY2020	
		Change (%)		Change (%)
Net sales	59,146	4.2	56,736	3.4
Operating income	3,571	13.8	3,137	(22.1)
Ordinary income	3,733	7.1	3,486	(4.3)
Profit attributable to owners of parent	1,943	(18.1)	2,373	24.3
Earnings per share (Yen)	107.44		131.26	
Diluted net income per share (Yen)	—		—	

Reference: Comprehensive income: 3rd quarter FY2021: ¥2,682 million (down 1.9% YoY)
3rd quarter FY2020: ¥2,733 million (up 141.1% YoY)

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

	End Q3 FY2021	Year End FY2020
Total assets	93,107	89,517
Net assets	36,218	34,011
Equity ratio (%)	27.5	26.4
Book value per share (Yen)	1,416.53	1,306.08

Reference: Shareholders' equity: 3rd quarter FY2021: ¥25,625 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 3rd Quarter Ended June 30, 2021

(1) Consolidated Balance Sheets

(Millions of yen)

	Q3 FY2021 (June 30, 2021)	Year End FY2020 (September 30, 2020)
Assets		
Current assets		
Cash and deposits	11,354	12,690
Notes and accounts receivable - trade	14,880	13,211
Merchandise and finished goods	709	729
Work in process	4,946	3,985
Raw materials and supplies	2,894	3,196
Other	4,296	3,696
Allowance for doubtful accounts	(58)	(66)
Total current assets	39,023	37,443
Non-current assets		
Property, plant and equipment		
Buildings and structures, net	15,669	15,221
Machinery, equipment and vehicles, net	11,464	12,008
Land	6,475	6,425
Other, net	8,539	6,603
Total property, plant and equipment	42,148	40,258
Intangible assets		
Goodwill	59	76
Other	1,821	1,645
Total intangible assets	1,881	1,721
Investments and other assets		
Investment securities	3,988	3,962
Lease and guarantee deposits	1,978	1,971
Other	4,683	4,727
Allowance for doubtful accounts	(598)	(567)
Total investments and other assets	10,052	10,093
Total non-current assets	54,083	52,074
Total assets	93,107	89,517

(Millions of yen)

	Q3 FY2021 (June 30, 2021)	Year End FY2020 (September 30, 2020)
Liabilities		
Current liabilities		
Notes and accounts payable — trade	915	1,019
Short-term borrowings	1,818	6,004
Current portion of long-term debt	3,595	3,258
Commercial papers	3,000	3,000
Income taxes payable	1,560	586
Provision for bonuses	693	2,413
Provision for loss on orders received	891	824
Other	14,321	12,084
Total current liabilities	26,796	29,191
Non-current liabilities		
Long-term debt	13,340	10,321
Net defined benefit liability	10,241	9,931
Other	6,509	6,061
Total non-current liabilities	30,091	26,314
Total liabilities	56,888	55,506
Net assets		
Shareholders' equity		
Capital stock	3,087	3,087
Capital surplus	6,100	6,100
Retained earnings	16,520	15,052
Treasury shares	(1,546)	(1,545)
Total shareholders' equity	24,162	22,694
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	1,433	1,336
Foreign currency translation adjustments	14	(29)
Remeasurements of defined benefit plans	15	(373)
Total accumulated other comprehensive income	1,462	933
Non-controlling interests	10,593	10,384
Total net assets	36,218	34,011
Total liabilities and net assets	93,107	89,517

(2) Consolidated Statement of Income

(Millions of yen)

	Q3 FY2021 (October 1, 2020— June 30, 2021)	Q3 FY2020 (October 1, 2019— June 30, 2020)
Net sales	59,146	56,736
Cost of sales	46,402	44,710
Gross profit	12,744	12,026
Selling, general and administrative expenses	9,173	8,888
Operating income	3,571	3,137
Non-operating income		
Interest income	1	3
Foreign exchange gains	146	—
Share of profit of entities accounted for using equity method	20	401
Subsidy income	94	33
Other	66	81
Total non-operating income	329	519
Non-operating expenses		
Interest expenses	99	89
Foreign exchange losses	—	45
Other	67	35
Total non-operating expenses	166	170
Ordinary income	3,733	3,486
Extraordinary income		
Gain on sales of non-current assets	—	5
Gain on sales of investment securities	—	10
Gain on sales of shares of subsidiaries and associates	19	30
Gain on forgiveness of debts	117	—
Total extraordinary income	136	46
Extraordinary losses		
Loss on retirement of non-current assets	56	75
Loss on valuation of investment securities	39	—
Total extraordinary losses	95	75
Profit before income taxes	3,774	3,457
Total income taxes	1,626	877
Profit	2,147	2,579
Profit attributable to non-controlling interests	203	205
Profit attributable to owners of parent	1,943	2,373

(3) Consolidated Statement of Comprehensive Income

(Millions of yen)

	Q3 FY2021 (October 1, 2020— June 30, 2021)	Q3 FY2020 (October 1, 2019— June 30, 2020)
Profit	2,147	2,579
Other comprehensive income		
Valuation difference on available-for-sale securities	96	110
Foreign currency translation adjustments	39	(13)
Remeasurements of defined benefit plans	400	57
Share of other comprehensive income of entities accounted for using equity method	(1)	—
Total other comprehensive income	535	154
Comprehensive income	2,682	2,733
Comprehensive income attributable to		
Owners of parent	2,473	2,500
Non-controlling interests	209	233