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July 29, 2019

CMIC HOLDINGS Co., Ltd. Consolidated Financial Results For the 3rd Quarter Ended June 30, 2019

(The Fiscal Year Ending September 30, 2019, Japan Accounting Standards)

Highlights:

- · Sales grew 6.3% year on year to ¥54.855 billion on a consolidated basis
- · Operating income increased 0.3% to ¥4.028 billion
- · Earnings per share ¥103.04

Tokyo, July 29, 2019 – CMIC HOLDINGS Co., Ltd. (TSE Code: 2309) today reported financial results for the 3rd quarter ended June 30, 2019

CMIC group is rolling out a PVC (Pharmaceutical Value Creator) model, which is our unique business model contributing to increase 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 licensing (intellectual properties) and value chains.

In the pharmaceutical industry, while creation of innovative drugs is anticipated towards providing personalized medicine or "precision medicine", drug pricing system is being revised, such as introduction of cost-effective assessments and consideration of special or specified medical care coverage, due to impact on the health insurance budget. Further improvement of productivity and technical capability is expected for the pharmaceutical industry for transformation to the industrial structure with more global competitiveness. New technologies called the Fourth Industrial Revolution such as artificial intelligence (AI) or IoT are bringing significant changes to the society, and as way of medicine and people's ideas of health change in the healthcare arena, industry, government, academia and civil society are collaborating to achieve innovation to address the decreasing birthrate and aging population.

The CMIC Group has been promoting "Project Phoenix" to adapt ourselves to the rapidly changing external environment in a timely and flexible manner and to achieve sustainable growth. We have started "Project Phoenix 3.0" in April 2018 to expand the application of our unique business model "PVC" (that provides end-to-end support for pharmaceutical companies) to the healthcare arena and promote new business creation. In addition, to achieve the mid-to-long-term corporate value improvement of our group, the mid-term plan (FY2019-2021) has started from this fiscal year that includes focus activity items such as acceleration of PVC model, expansion of globalization, and creation of healthcare business. We are implementing various group-wide measures to execute such activities.

Sales and Operating Income

In the 3rd quarter of the current fiscal year, CMIC succeeded Astellas Pharma Tech Nishine Plant to increase the manufacturing capabilities of our CDMO business with 6 domestic and overseas plants. Further, we are addressing the top-priority issues identified in the mid-term plan such as starting services for self-collect HPV test "SelCheck Cervical Cancer" and "harmo", the electronic prescription record service transferred from Sony Corporation. Sales in the 3rd quarter of fiscal year 2019 was ¥54.855 billion (grew 6.3% year-on-year) primarily driven by the CRO business growth. Operating income was ¥4.028 billion (up 0.3% year-on-year).

Segment Information

The business results by segment are listed as below:

CRO (Contract Research Organization) Business

_				(Millions of yen)
	Q3 FY2019	Q3 FY2018	YoY Change	YoY Change
	Q3 F12019	Q3 F12010	Amount	%
Sales	29,199	27,960	+1,239	+4.4
Operating income	5,962	5,904	+57	+1.0

In this business, we provide services primarily to pharmaceutical companies to support drug development. In the 3rd quarter of the current fiscal year, we are supporting overseas companies entering the Japanese market and non-healthcare companies entering the healthcare sphere, promoting measures to address sophisticating development needs including biopharmaceuticals and regenerative medicines.

While striving to secure and train personnel to meet robust demand in clinical services, we are promoting the use of the medical database in PMS (Post Marketing Surveillance) or clinical research support business. Further, we are promoting business in the Asia and Oceania region, a growing market for drugs and medical devices, by establishing a local affiliate in Australia.

For non-clinical services, our laboratories in Japan and the United States are further collaborating to provide drug discovery support for advanced medicine including nucleic acid drugs and regenerative medicine. We have concluded the partnership agreement with Sophion Bioscience, a global pioneer in ion channel related business, in October 2018 to expand safety pharmacology services.

Sales and operating income exceeded those from the same period of the previous year thanks to robust growth in new and existing contracts.

• CDMO (Contract Development Manufacturing Organization) Business

-				(Millions of yen)
	Q3 FY2019	Q3 FY2018	YoY Change	YoY Change
	Q3 F12019	Q3 F12016	Amount	%
Sales	11,858	10,806	+1,052	+9.7
Operating income	(156)	(473)	+317	-

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

In the 3rd quarter of the current fiscal year, CDMO business is further improving technical capabilities, developing 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. In addition, the new parenteral drug manufacturing facility in Ashikaga with capabilities to formulate high potency drugs has started the clinical trial material production, and is enhancing the sales activities to manufacture both clinical trial materials and commercial drugs. In March 2019, CMIC has concluded business alliance agreements with U.S.-based corporations that possess 3DP technology platform and sophisticated flexible dosing tablet technology, to introduce new technologies for drug manufacturing and improve our formulation technologies. In June 2019, CMIC CMO has succeeded the Nishine Plant from Astellas Pharma Tech, Astellas' production subsidiary in Japan, and CMIC CMO NISHINE Co., Ltd. has started its operations to increase the manufacturing capabilities for the oral solid dose, our main dosage form. Sales exceeded that of the same period last year mainly due to increase of contract production sales in Japan and the United States. While operating loss was recorded due to commercial production start-up expenses and increased depreciation cost for the new parenteral drug manufacturing facility in Ashikaga, the loss amount shows decreasing trend.

CSO (Contract Sales Organization) Business

<u>-</u>				(Millions of yen)
	Q3 FY2019	O2 EV2019	YoY Change	YoY Change
	Q3 F12019	Q3 FY2018	Amount	%
Sales	5,795	5,479	+316	+5.8
Operating income	100	349	(248)	(71.1)

In this business, we provide sales- and marketing-support services, primarily to pharmaceutical companies. In the 3rd quarter of the current fiscal year, in addition to the medical representative (MR) dispatch service, CMIC Ashfield Co., Ltd. is providing comprehensive solution that combines multiple communication channels and various services including the opening of "MA academy", the first private sector institution to train Medical Affairs (MA) personnel.

Sales exceeded that of the same period of the previous year thanks to the steady execution of both new and existing projects. However, operating profit was below that of the same period last year due to the preceding costs generated to take on new projects.

Healthcare Business

_				(Millions of yen)
	Q3 FY2019	O2 EV2019	YoY Change	YoY Change
	Q3 F12019	Q3 FY2018	Amount	%
Sales	5,700	5,432	+267	+4.9
Operating income	703	668	+35	+5.2

In this business, we provide site management organization (SMO) and healthcare information services, primarily to medical institutions, patients, and general consumers, to support maintaining and promoting health and healthcare.

In the 3rd quarter of the current fiscal year, we are further strengthening the oncology capabilities in the SMO operations, improving the quality of our operations, and providing new services. In April 2019, BELL24-Cell Product, Inc. (now SSI-CP Co., Ltd.) became our group company to further enhance our presence in Hokkaido. As healthcare information services, we are providing information of clinical trials using the healthcare portal site and starting the "SelCheck" (self-screening) services for early detection and prevention of aggravation of disease. In June 2019, we succeeded "harmo", the electronic prescription record service, from Sony Corporation to enhance patient support programs including treatment adherence improvement and to create health support business utilizing technologies.

Sales and operating income both exceeded those of the same period of the previous year thanks to the steady execution of new projects.

IPM (Innovative Pharma Model) Business

<u>-</u>				(Millions of yen)
	Q3 FY2019	Q3 FY2018	YoY Change	YoY Change
	Q31 12019	Q3 F 1 20 18	Amount	%
Sales	2,695	2,305	+390	+17.0
Operating income	(199)	(185)	(13)	-

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 our orphan drug business, OrphanPacific, Inc., is selling orphan drugs, including products developed in-house. Further, we are strengthening business foundation through provision of IPM platform such as supporting foreign companies entering the Japanese market and providing strategic options to pharmaceutical companies in accordance with their business model changes.

In the diagnostics business, we are working to expand the market and strengthen promotions of the kidney disease biomarker "human L-type fatty acid-binding protein (L-FABP) kit", developed for the purpose of diagnosing renal disease.

Sales exceeded that of the same period of the previous year due to sales increase of orphan drugs. We are continuing to expand our business scale through provision of new solutions aiming for positive turnaround.

Ordinary Income

Ordinary income for the 3rd guarter of the current fiscal year was ¥3,643 million (down 4.3% YoY).

For non-operating income, we recorded ¥73 million of rent income and others, and for non-operating expenses we recorded ¥458 million of interest expense, share of loss of entities accounted for using equity method, and foreign exchange losses.

Profit attributable to owners of parent

Current profit attributable to owners of parent for the 3rd quarter of the current fiscal year was ¥1,909 million (up 55.3% YoY).

For extraordinary income, we recorded ¥7 million as gain on sales of non-current assets, and as for extraordinary losses, we recorded ¥190 million as impairment loss, loss on retirement of non-current assets and other. ¥1,823 million was recorded as total income taxes, and ¥272 million as loss attributable to non-controlling interests.

Overview of the financial condition

Assets, liabilities, and net assets

Total assets at the end of the 3rd quarter of the current fiscal year increased by ¥2,643 million YoY to ¥80.677 billion. This is mainly due to increase inventories and tangible fixed assets following the acquisition of CMIC CMO NISHINE Co., Ltd.

Total liabilities increased by ¥2,539 million YoY to ¥47.037 billion. This is mainly due to increase of short-term loans payable and commercial paper issuances, and decrease in provision for bonuses and long-term loans payable (including the current portion).

Total net assets increased by ¥103 million YoY to ¥33.639 billion. This is mainly due to an increase in retained earnings, decrease in valuation difference on available-for-sale securities, and purchase of treasury stock. In addition, "Partial Amendments to Accounting Standard for Tax Effect Accounting" (ASBJ Statement No. 28, February 16, 2018) has been applied since the beginning of the first quarter consolidated accounting period, and the financial results are compared based on the Consolidated Financial Statements for the previous fiscal year after the amendments are retrospectively applied.

Future Outlook

There are no changes from the consolidated performance forecast (CMIC HOLDINGS Co., Ltd. Consolidated Financial Results for the year ended September 30, 2018) announced on November 7, 2018.

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, 2019 (October 1, 2018 through June 30, 2019)

(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)

	Q3 F	Y2019	Q3 FY	2018
		Change		Change
		(%)		(%)
Net sales	54,855	6.3	51,624	7.6
Operating income	4,028	0.3	4,016	37.4
Ordinary income	3,643	(4.3)	3,805	33.3
Profit attributable to owners of parent	1,909	55.3	1,229	19.9
Earnings per share (Yen)	103.04		65.75	
Diluted net income per share (Yen)	_		_	

Reference: Comprehensive income: 3rd quarter FY2019: ¥1,133 million (down 29.7% YoY), 3rd quarter FY2018: ¥1,613 million (down 20.2% YoY)

(2) Consolidated financial position

(Millions of yen; amounts less than one million yen are omitted)

	Q3 FY2019	Year End FY2018
Total assets	80,677	78,034
Net assets	33,639	33,536
Equity ratio (%)	28.5	28.9
Book value per share (Yen)	1,255.24	1,215.95

Reference: Shareholders' equity: 3rd quarter FY2019: ¥22,996 million, year-end FY2018: ¥22,582 million.

Distribution of Profits and Dividends

In the fiscal year ending September 30, 2019, the Company plans to make two payments of dividends – an interim payment at ¥5.00 and a year-end payment at ¥27.00 –, totaling to an annual payment of ¥32.00.

Consolidated Financial Statements for the 3rd Quarter Ended June 30, 2019

(1) Consolidated Balance Sheets

(Mil	lions of y	en)
= n d	EV2019	

	O2 EV2010	Year End FY2018
	Q3 FY2019	
	(June 30, 2019)	(September 30, 2018)
Assets		
Current assets		
Cash and deposits	12,789	14,009
Notes and accounts receivable - trade	14,191	13,655
Merchandise and finished goods	692	514
Work in process	3,987	3,419
Raw materials and supplies	2,595	1,878
Other	3,345	2,773
Allowance for doubtful accounts	(17)	(18)
Total current assets	37,582	36,233
Noncurrent assets		
Property, plant and equipment		
Buildings and structures, net	12,878	12,533
Machinery, equipment and vehicles, net	9,727	5,522
Land	6,433	6,167
Other, net	3,866	6,284
Total property, plant and equipment	32,905	30,508
Intangible assets		
Goodwill	313	419
Other	1,472	985
Total intangible assets	1,785	1,405
Investments and other assets		
Investment securities	3,219	3,809
Lease and guarantee deposits	1,737	1,655
Other	4,029	5,032
Allowance for doubtful accounts	(582)	(611)
Total investments and other assets	8,403	9,887
Total non-current assets	43,095	41,801
Total assets	80,677	78,034

		(Millions of yen
	Q3 FY2019	Year End FY2018
	(June 30, 2019)	(September 30, 2018)
Liabilities		
Current liabilities		
Notes and accounts payable – trade	982	726
Short-term borrowings	3,018	1,450
Current portion of long-term debt	2,636	3,648
Commercial papers	3,000	2,000
Income taxes payable	124	1,076
Provision for bonuses	1,122	2,655
Provision for directors' bonuses	-	63
Provision for loss on orders received	576	683
Other	11,413	10,438
Total current liabilities	22,872	22,741
Non-current liabilities		
Long-term debt	12,061	12,178
Net defined benefit liability	8,053	7,544
Other	4,049	2,033
Total non-current liabilities	24,165	21,756
Total liabilities	47,037	44,498
Net assets		
Shareholders' equity		
Capital stock	3,087	3,087
Capital surplus	6,102	6,102
Retained earnings	14,207	12,814
Treasury stock	(1,088)	(579)
Total shareholders' equity	22,310	21,425
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	751	1,217
Foreign currency translation adjustments	(21)	23
Remeasurements of defined benefit plans	(43)	(83)
Total accumulated other comprehensive income	686	1,157
Non-controlling interests	10,643	10,953
Total net assets	33,639	33,536
Total liabilities and net assets	80,677	78,034

2) Consolidated Statement of Income		(Millions of yer
	Q3 FY2019	Q3 FY2018
	(October 1, 2018–	(October 1, 2017-
	June 30, 2019)	June 30, 2018)
Net sales	54,855	51,624
Cost of sales	42,349	39,936
Gross profit	12,506	11,687
Selling, general and administrative expenses	8,477	7,671
Operating income	4,028	4,016
Non-operating income		
Interest income	3	4
Rent income	17	14
Insurance Income	15	-
Refunded consumption taxes	15	12
Other	23	24
Total non-operating income	73	56
Non-operating expenses		
Interest expenses	84	87
Share of loss of entities accounted for using equity method	162	91
Foreign exchange losses	173	39
Other	38	48
Total non-operating expenses	458	266
Ordinary income	3,643	3,805
Extraordinary income		
Gain on sales of non-current assets	7	-
Total extraordinary income	7	-
Extraordinary losses		
Impairment loss	124	-
Loss on sales of non-current assets	1	0
Loss on retirement of non-current assets	65	46
Loss on valuation of investment securities	-	4
Loss on revision of pay regulations	-	280
Total extraordinary losses	190	333
Profit before income taxes	3,460	3,472
Current	1,080	1,282
Deferred	742	912
Total income taxes	1,823	2,194
Profit	1,637	1,277
Profit (loss) attributable to non-controlling interests	(272)	48
Profit attributable to owners of parent	1,909	1,229

(3) Consolidated Statement of Comprehensive Income

(Millions of yen)

	(Willion or you)
Q3 FY2019	Q3 FY2018
(October 1, 2018–	(October 1, 2017-
June 30, 2019)	June 30, 2018)
1,637	1,277
(467)	311
(95)	(54)
59	78
(503)	335
1,133	1,613
1,437	1,587
(304)	26
	(October 1, 2018– June 30, 2019) 1,637 (467) (95) 59 (503) 1,133