(Note) This translation is prepared and provided for readers' convenience only. In the event of any discrepancy between this translated document and the original Japanese document, the original document shall prevail.

April 26, 2019

# CMIC HOLDINGS Co., Ltd. Consolidated Financial Results For the 2<sup>nd</sup> Quarter Ended March 31, 2019

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

#### Highlights:

- · Sales grew 8.9% year on year to ¥36.633 billion on a consolidated basis
- · Operating income increased 16.5% to ¥2.879 billion
- · Earnings per share ¥82.72

Tokyo, April 26, 2019 – CMIC HOLDINGS Co., Ltd. (TSE Code: 2309) today reported financial results for the 2<sup>nd</sup> guarter ended March 31, 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 second quarter of the current fiscal year, to increase the competitiveness in the global market, we are addressing the top-priority issues identified in the mid-term plan such as building recognition and creating demand in the United States, building the regional healthcare network through the Consortium based on industry-government-academia-people collaboration, and starting services for self-collect HPV test "SelCheck Cervical Cancer." Sales in the second quarter of fiscal year 2019 was 36.633 billion (grew 8.9% year-on-year) primarily driven by the CRO business growth. Operating income was 2.879 billion (up 16.5% year-on-year).

#### **Segment Information**

The business results by segment are listed as below:

#### CRO (Contract Research Organization) Business

_				(Millions of yen)	
	1H FY2019	1H FY2018	YoY Change	YoY Change	
	10 112019	111712016	Amount	%	
Sales	19,947	18,553	+1,393	+7.5	
Operating income	4,306	3,929	+376	+9.6	

In this business, we provide services primarily to pharmaceutical companies to support drug development. In the second 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, and expanding our presence in Asia.

While striving to secure human resources 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.

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)	
	1H FY2019	1H FY2018	YoY Change	YoY Change	
	10 512019	IH F 12010	Amount	%	
Sales	7,724	6,786	+937	+13.8	
Operating income	(147)	(525)	+377	-	

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

In the second 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 December 2018, CMIC CMO has concluded a share transfer agreement with Astellas Pharma Tech, Astellas' production subsidiary in Japan, to succeed the Nishine Plant business in an effort to improve the oral solid dose manufacturing capabilities. Further, in March 2019, CMIC has formed business alliances with U.S.-based corporations that possess 3DP technology platform and sophisticated flexible dosing tablet technology, to introduce new technologies for drug manufacturing.

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 has decreased following the increase of contract manufacturing volume.

#### CSO (Contract Sales Organization) Business

<u>-</u>				(Millions of yen)	
	4U EV2040	4U EV2049	YoY Change	YoY Change	
	1H FY2019	1H FY2018	Amount	%	
Sales	3,701	3,486	+214	+6.2	
Operating income	(33)	153	(187)	-	

In this business, we provide sales- and marketing-support services, primarily to pharmaceutical companies. In the second 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 loss was recorded due to the costs generated to meet the increasing demand and take on large-scale projects including hiring and training costs.

#### Healthcare Business

<u>-</u>				(Millions of yen)
	1H FY2019	1H FY2018	YoY Change	YoY Change
	IH F12019	111112016	Amount	%
Sales	3,597	3,607	(10)	(0.3)
Operating income	416	465	(48)	(10.5)

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 second 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 February 2019, we have concluded the stock purchase agreement with BELL24-Cell Product, Inc. 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 March 2019, we concluded a formal agreement with Sony Corporation for the transfer of "harmo", the electronic prescription record service, to enhance the patient support program including the treatment adherence improvement.

While sales remain unchanged from the previous year, operating income are below that of the same period of the previous year due to the impact of discontinuation or temporary interruption of contract studies in SMO business operations.

#### IPM (Innovative Pharma Model) Business

_				(Millions of yen)
	1H FY2019	1H EV2019	YoY Change	YoY Change
	IH F12019	111712010	1H FY2018 Amount	%
Sales	1,881	1,420	+460	+32.4
Operating income	(108)	(111)	+3	

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 second quarter of the current fiscal year was ¥2,661 million (up 19.6% YoY). For non-operating income, we recorded ¥50 million of insurance income and others, and for non-operating expenses we recorded ¥268 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 second quarter of the current fiscal year was ¥1,536 million (up 214.1% YoY).

For extraordinary income, we recorded ¥6 million as gain on sales of non-current assets, and as for extraordinary losses, we recorded ¥174 million as impairment loss and loss on retirement of non-current assets. ¥1,142 million was recorded as total income taxes (down 307 million YoY), and ¥185 million as loss attributable to non-controlling interests.

Further, the decrease of total income taxes was mainly due to temporary increase of income taxes deferred in the previous second quarter consolidated cumulative period impacted by reversal of deferred tax assets, because CMIC CMO Co., Ltd., a fully owned subsidiary of CMIC Holdings Co., Ltd., became a joint venture and withdrew from the CMIC Group consolidated tax return filing system.

#### Overview of the financial condition

Assets, liabilities, and net assets

Total assets at the end of the second quarter of the current fiscal year increased by ¥859 million YoY to ¥78.894 billion. This is mainly due to a decrease in notes and accounts receivable and investment securities against an increase in cash and deposits.

Total liabilities increased by ¥503 million YoY to ¥45.001 billion. This is mainly due to an increase of commercial paper issuances and decrease in long-term loans payable (including the current portion).

Total net assets increased by ¥356 million YoY to ¥33.892 billion. This is mainly due to an increase in retained earnings and decrease in valuation difference on available-for-sale securities.

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 2<sup>nd</sup> Quarter Ended March 31, 2019 (October 1, 2018 through March 31, 2019)

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

	1H F	Y2019	1H FY	2018
		Change		Change
		(%)		(%)
Net sales	36,633	8.9	33,640	6.0
Operating income	2,879	16.5	2,471	29.9
Ordinary income	2,661	19.6	2,225	17.9
Profit attributable to owners of parent	1,536	214.1	489	(8.4)
Earnings per share (Yen)	82.72		26.14	
Diluted net income per share (Yen)	_		_	

Reference: Comprehensive income: 2<sup>nd</sup> quarter FY2019: ¥783 million (down 38.6% YoY), 2<sup>nd</sup> quarter FY2018: ¥1,274 million (up 15.1% YoY)

(2) Consolidated financial position (Millions o

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

	Q2 FY2019	Year End FY2018
Total assets	78,894	78,034
Net assets	33,892	33,536
Equity ratio (%)	29.3	28.9
Book value per share (Yen)	1,245.85	1,215.95

Reference: Shareholders' equity: 2<sup>nd</sup> quarter FY2019: ¥23,139 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 2<sup>nd</sup> Quarter Ended March 31, 2019

# (1) Consolidated Balance Sheets

(Millions of yen
------------------

	Q2 FY2019	Year End FY2018
	(March 31, 2019)	(September 30, 2018)
Assets		
Current assets		
Cash and deposits	14,939	14,009
Notes and accounts receivable - trade	14,460	13,655
Merchandise and finished goods	713	514
Work in process	3,200	3,419
Raw materials and supplies	1,795	1,878
Other	2,972	2,773
Allowance for doubtful accounts	(18)	(18)
Total current assets	38,063	36,233
Noncurrent assets		
Property, plant and equipment		
Buildings and structures, net	12,409	12,533
Machinery, equipment and vehicles, net	9,350	5,522
Land	6,156	6,167
Other, net	2,962	6,284
Total property, plant and equipment	30,879	30,508
Intangible assets		
Goodwill	278	419
Other	1,016	985
Total intangible assets	1,295	1,405
Investments and other assets		
Investment securities	3,031	3,809
Lease and guarantee deposits	1,655	1,655
Other	4,556	5,032
Allowance for doubtful accounts	(597)	(611)
Total investments and other assets	8,655	9,887
Total non-current assets	40,830	41,801
Total assets	78,894	78,034

		(Millions of yen)
	Q2 FY2019	Year End FY2018
	(March 31, 2019)	(September 30, 2018)
Liabilities		
Current liabilities		
Notes and accounts payable – trade	819	726
Short-term borrowings	1,484	1,450
Current portion of long-term debt	2,455	3,648
Commercial papers	4,000	2,000
Income taxes payable	685	1,076
Provision for bonuses	2,108	2,655
Provision for directors' bonuses	-	63
Provision for loss on orders received	657	683
Other	10,735	10,438
Total current liabilities	22,945	22,741
Non-current liabilities		
Long-term debt	12,767	12,178
Net defined benefit liability	7,778	7,544
Other	1,509	2,033
Total non-current liabilities	22,055	21,756
Total liabilities	45,001	44,498
Net assets		
Shareholders' equity		
Capital stock	3,087	3,087
Capital surplus	6,102	6,102
Retained earnings	13,928	12,814
Treasury stock	(578)	(579)
Total shareholders' equity	22,540	21,425
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	634	1,217
Foreign currency translation adjustments	20	23
Remeasurements of defined benefit plans	(56)	(83)
Total accumulated other comprehensive income	598	1,157
Non-controlling interests	10,753	10,953
Total net assets	33,892	33,536
Total liabilities and net assets	78,894	78,034

2) Consolidated Statement of Income		(Millions of y
	1H FY2019	1H FY2018
	(October 1, 2018–	(October 1, 2017-
	March 31, 2019)	March 31, 2018)
Net sales	36,633	33,640
Cost of sales	28,240	26,116
Gross profit	8,392	7,523
Selling, general and administrative expenses	5,513	5,051
Operating income	2,879	2,471
Non-operating income		
Interest income	2	3
Rent income	11	3
Refunded consumption taxes	10	8
Insurance Income	15	
Other	11	19
Total non-operating income	50	39
Non-operating expenses		
Interest expenses	56	57
Share of loss of entities accounted for using equity method	108	59
Foreign exchange losses	77	131
Other	25	36
Total non-operating expenses	268	285
Ordinary income	2,661	2,225
Extraordinary income		
Gain on sales of non-current assets	6	
Total extraordinary income	6	
Extraordinary losses		
Impairment loss	124	
Loss on sales of non-current assets	-	(
Loss on retirement of non-current assets	50	28
Loss on valuation of investment securities	-	4
Loss on revision of pay regulations	-	252
Total extraordinary losses	174	287
Profit before income taxes	2,493	1,938
Current	1,035	1,038
Deferred	107	412
Total income taxes	1,142	1,450
Profit	1,350	488
Loss attributable to non-controlling interests	(185)	(0
Profit attributable to owners of parent	1,536	489

## (3) Consolidated Statement of Comprehensive Income

(Millions of yen)

		(Willion or you)
	1H FY2019	1H FY2018
	(October 1, 2018–	(October 1, 2017-
	March 31, 2019)	March 31, 2018)
Profit	1,350	488
Other comprehensive income		
Valuation difference on available-for-sale securities	(583)	766
Foreign currency translation adjustments	(23)	(32)
Remeasurements of defined benefit plans	39	53
Total other comprehensive income	(567)	786
Comprehensive income	783	1,274
Comprehensive income attributable to		
Owners of parent	977	1,293
Non-controlling interests	(194)	(19)

## (4) Consolidated Statement of Cash Flows

(Millions of yen)	1H FY 2019	1H FY 2018
	(October 1, 2018– March 31, 2019)	(October 1, 2017– March 31, 2018)
sh flows from operating activities:		
Profit before income taxes	2,493	1,938
Depreciation	1,728	1,511
Impairment loss	124	-
Amortization of goodwill	140	177
Increase (decrease) in allowance for doubtful	0	2
accounts	U	2
Increase (decrease) in provision for bonuses	(546)	(351)
Increase (decrease) in provision for directors' bonuses	(63)	(53)
Increase (decrease) in net defined benefit liability	285	508
Interest and dividend income	(2)	(3)
Interest expenses	56	57
Foreign exchange losses (gains)	68	105
Share of loss (profit) of entities accounted for using	108	59
equity method		
Decrease (increase) in notes and accounts receivable	(836)	(47)
- trade		
Decrease (increase) in inventories	92	(217)
Increase (decrease) in notes and accounts payable -	102	(22)
trade	102	(32)
Increase (decrease) in accrued expenses	(89)	(48)
Increase (decrease) in advances received	196	404
Other, net	(578)	(617)
Subtotal	3,281	3,394
Interest and dividend income received	14	43
Interest expenses paid	(66)	(77)
Income taxes paid	(1,488)	(1,376)
Proceeds from subsidy income	2	2
Net cash provided by (used in) operating activities	1,744	1,986
Cash flows from investing activities		
Proceeds from withdrawal of time deposits	29	17
Purchase of property, plant and equipment	(1,374)	(4,039)
Purchase of intangible assets	(287)	(114)

Payments for lease and guarantee deposits	(42)	(44)
Proceeds from collection of lease and guarantee	30	24
deposits		
Other, net	16	0
Net cash provided by (used in) investing activities	(1,687)	(4,266)
Cash flows from financing activities		
Net increase (decrease) in short-term loans	34	3,500
payable		
Net increase (decrease) in commercial papers	2,000	-
Proceeds from long-term loans payable	2,000	1,200
Repayments of long-term loans payable	(2,604)	(1,250)
Repayments of lease obligations	(70)	(103)
Purchase of treasury shares	(0)	(2)
Cash dividends paid	(420)	(424)
Dividends paid to non-controlling interests	(6)	(66)
Net cash provided by (used in) financing activities	931	2,853
Effect of exchange rate change on cash and cash	(28)	(40)
equivalents	(20)	(40)
Net increase (decrease) in cash and cash equivalents	960	533
Cash and cash equivalents at beginning of period	13,976	4,928
Increase in cash and cash equivalents from newly		19
consolidated subsidiary		19
Cash and cash equivalents at end of period	14,937	5,481