

(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.

February 1, 2019

## **CMIC HOLDINGS Co., Ltd. Consolidated Financial Results For the 1<sup>st</sup> Quarter Ended December 31, 2018**

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

### **Highlights:**

- **Sales grew 4.6% year on year to ¥17.399 billion on a consolidated basis**
- **Operating income decreased 4.8% to ¥965 million, proceeding according to plan**
- **Earnings per share ¥28.89**
- **Order backlog of contract services grew 1.9% year on year to ¥73.501 billion**

Tokyo, February 1, 2019 – CMIC HOLDINGS Co., Ltd. ( TSE Code: 2309 ) today reported financial results for the 1<sup>st</sup> quarter ended December 31, 2018

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 first 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, starting the Consortium through industry-government-academia collaboration, and supporting the establishment of a regional healthcare network. Sales in the first quarter of fiscal year 2019 was 17.399 billion (grew 4.6% year-on-year) driven by the CRO business growth. Operating income was 965 million (down 4.8% year-on-year) mainly due to decrease in profits of CDMO business, but overall it is progressed as planned.

## Segment Information

The business results by segment are listed as below:

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

	(Millions of yen)			
	Q1 FY2019	Q1 FY2018	YoY Change Amount	YoY Change %
Sales	9,674	9,012	+ 662	+ 7.3
Operating income	2,121	1,812	+ 309	+ 17.0

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

In the first 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 sophisticated 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)

	Q1 FY2019	Q1 FY2018	YoY Change Amount	YoY Change %
Sales	3,384	3,586	(202)	(5.6)
Operating income	(377)	(184)	(193)	-

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

In the first 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.

Sales were less than the same period of the previous year mainly due to production schedule changes.

Operating loss was recorded following the commercial production start-up expenses for the new parenteral drug manufacturing facility in Ashikaga and increased depreciation cost.

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

(Millions of yen)

	Q1 FY2019	Q1 FY2018	YoY Change Amount	YoY Change %
Sales	1,782	1,675	+107	+6.4
Operating income	(44)	56	(100)	-

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

In the first quarter of the current fiscal year, in addition to the medical representative (MR) dispatch and other related services, CMIC Ashfield Co., Ltd. is providing comprehensive solution that combines multiple communication channels and various services including dispatch and training of Medical Affairs personnel.

Sales exceeded that of the same period of the previous year thanks to the steady execution of existing projects, but 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**

	(Millions of yen)			
	Q1 FY2019	Q1 FY2018	YoY Change Amount	YoY Change %
Sales	1,699	1,739	(39)	(2.3)
Operating income	106	149	(42)	(28.6)

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 first quarter of the current fiscal year, we are further strengthening the oncology capabilities in the SMO operations, improving the quality of our operations and services, and providing new services. In addition, we are enhancing services for patients by providing information of clinical trials using the healthcare portal site and preparing for the introduction of 'self-checks' (also known as self-examinations or self-exams) services.

Sales and operating income are below that of the same period of the previous year due to discontinuation or temporary interruption of contract studies in SMO business operations.

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

	(Millions of yen)			
	Q1 FY2019	Q1 FY2018	YoY Change Amount	YoY Change %
Sales	954	746	+208	+27.9
Operating income	(12)	(65)	+52	-

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 first quarter of the current fiscal year was ¥861 million (down 16.8% YoY).

For non-operating income, we recorded ¥32 million, and for non-operating expenses we recorded ¥135 million of interest expense, foreign exchange loss, and share of loss of entities accounted for using equity method.

## Profit attributable to owners of parent

Current profit attributable to owners of parent for the first quarter of the current fiscal year was ¥536 million (down 1.4% YoY).

For extraordinary income, we recorded ¥6 million as gain on sale of non-current assets, and as for extraordinary loss, we recorded ¥47 million as loss on retirement of non-current assets. ¥551 million was recorded as total income taxes, and ¥267 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 first quarter of the current fiscal year decreased by ¥80 million YoY to ¥77.954 billion. This is mainly due to a decrease in notes and accounts receivable and investment securities against an increase in cash and deposits.

As for tangible fixed assets, construction in progress (Other, net in Property, plant and equipment) was transferred to machinery, equipment and vehicles, net, following the start of operation of the new injection building for the CDMO business (Ashikaga Plant).

Total liabilities increased by ¥782 million YoY to ¥45.280 billion. This is mainly due to a decrease in provision for bonus and income taxes payable against the increase in short-term borrowings and commercial paper.

Total net assets decreased by ¥862 million YoY to ¥32.673 billion. This is mainly due to a decrease in valuation difference on available-for-sale securities.

## 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 1st Quarter Ended December 31, 2018 (October 1, 2018 through December 31, 2018)**

(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)

	Q1 FY2019		Q1 FY2018	
		Change (%)		Change (%)
Net sales	17,399	4.6	16,637	8.1
Operating income	965	(4.8)	1,013	102.0
Ordinary income	861	(16.8)	1,035	67.1
Profit attributable to owners of parent	536	(1.4)	544	170.9
Earnings per share (Yen)	28.89		29.09	
Diluted net income per share (Yen)	—		—	

Reference: Comprehensive income: 1<sup>st</sup> quarter FY2019: ¥(434) million (-), 1<sup>st</sup> quarter FY2018: ¥660 million (up 29.9% YoY)

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

	Q1 FY2019	Year End FY2018
Total assets	77,954	78,034
Net assets	32,673	33,536
Equity ratio (%)	28.2	28.9
Book value per share (Yen)	1,184.86	1,215.95

Reference: Shareholders' equity: 1<sup>st</sup> quarter FY2019: ¥22,005 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 1st Quarter Ended December 31, 2018

(1) Consolidated Balance Sheets

(Millions of yen)

	Q1 FY2019 (December 31, 2018)	Year End FY2018 (September 30, 2018)
<b>Assets</b>		
<b>Current assets</b>		
Cash and deposits	15,441	14,009
Notes and accounts receivable - trade	13,032	13,655
Merchandise and finished goods	613	514
Work in process	3,608	3,419
Raw materials and supplies	1,948	1,878
Other	3,068	2,773
Allowance for doubtful accounts	(18)	(18)
<b>Total current assets</b>	<b>37,695</b>	<b>36,233</b>
<b>Noncurrent assets</b>		
Property, plant and equipment		
Buildings and structures, net	12,417	12,533
Machinery, equipment and vehicles, net	9,482	5,522
Land	6,160	6,167
Other, net	2,461	6,284
<b>Total property, plant and equipment</b>	<b>30,521</b>	<b>30,508</b>
Intangible assets		
Goodwill	349	419
Other	921	985
<b>Total intangible assets</b>	<b>1,270</b>	<b>1,405</b>
Investments and other assets		
Investment securities	2,876	3,809
Lease and guarantee deposits	1,673	1,655
Other	4,515	5,032
Allowance for doubtful accounts	(598)	(611)
<b>Total investments and other assets</b>	<b>8,466</b>	<b>9,887</b>
<b>Total non-current assets</b>	<b>40,258</b>	<b>41,801</b>
<b>Total assets</b>	<b>77,954</b>	<b>78,034</b>

(Millions of yen)

	Q1 FY2019 (December 31, 2018)	Year End FY2018 (September 30, 2018)
<b>Liabilities</b>		
<b>Current liabilities</b>		
Notes and accounts payable – trade	781	726
Short-term borrowings	2,084	1,450
Current portion of long-term debt	2,274	3,648
Commercial papers	5,000	2,000
Income taxes payable	51	1,076
Provision for bonuses	568	2,655
Provision for directors' bonuses	-	63
Provision for loss on orders received	585	683
Other	11,145	10,438
<b>Total current liabilities</b>	<b>22,489</b>	<b>22,741</b>
<b>Non-current liabilities</b>		
Long-term debt	13,473	12,178
Net defined benefit liability	7,675	7,544
Other	1,641	2,033
<b>Total non-current liabilities</b>	<b>22,790</b>	<b>21,756</b>
<b>Total liabilities</b>	<b>45,280</b>	<b>44,498</b>
<b>Net assets</b>		
<b>Shareholders' equity</b>		
Capital stock	3,087	3,087
Capital surplus	6,102	6,102
Retained earnings	12,928	12,814
Treasury stock	(579)	(579)
<b>Total shareholders' equity</b>	<b>21,540</b>	<b>21,425</b>
<b>Accumulated other comprehensive income</b>		
Valuation difference on available-for-sale securities	521	1,217
Foreign currency translation adjustments	13	23
Remeasurements of defined benefit plans	(70)	(83)
<b>Total accumulated other comprehensive income</b>	<b>465</b>	<b>1,157</b>
<b>Non-controlling interests</b>	<b>10,668</b>	<b>10,953</b>
<b>Total net assets</b>	<b>32,673</b>	<b>33,536</b>
<b>Total liabilities and net assets</b>	<b>77,954</b>	<b>78,034</b>



## (2) Consolidated Statement of Income

(Millions of yen)

	Q1 FY2019 (October 1, 2018– December 31, 2018)	Q1 FY2018 (October 1, 2017– December 31, 2017)
<b>Net sales</b>	<b>17,399</b>	<b>16,637</b>
<b>Cost of sales</b>	<b>13,677</b>	<b>13,065</b>
<b>Gross profit</b>	<b>3,721</b>	<b>3,572</b>
<b>Selling, general and administrative expenses</b>	<b>2,756</b>	<b>2,558</b>
<b>Operating income</b>	<b>965</b>	<b>1,013</b>
<b>Non-operating income</b>		
Interest income	1	1
Share of profit of entities accounted for using equity method	-	16
Foreign exchange gains	-	26
Rent income	5	2
Refunded consumption taxes	4	3
Insurance Income	14	-
Other	6	8
<b>Total non-operating income</b>	<b>32</b>	<b>59</b>
<b>Non-operating expenses</b>		
Interest expenses	32	28
Share of loss of entities accounted for using equity method	35	-
Foreign exchange losses	56	-
Other	11	9
<b>Total non-operating expenses</b>	<b>135</b>	<b>37</b>
<b>Ordinary income</b>	<b>861</b>	<b>1,035</b>
<b>Extraordinary income</b>		
Gain on sales of non-current assets	6	-
<b>Total extraordinary income</b>	<b>6</b>	<b>-</b>
<b>Extraordinary losses</b>		
Loss on retirement of non-current assets	47	13
Loss on valuation of investment securities	-	4
<b>Total extraordinary losses</b>	<b>47</b>	<b>18</b>
<b>Profit before income taxes</b>	<b>820</b>	<b>1,016</b>
Current	36	77
Deferred	514	398
<b>Total income taxes</b>	<b>551</b>	<b>475</b>
<b>Profit</b>	<b>269</b>	<b>540</b>
<b>Loss attributable to non-controlling interests</b>	<b>(267)</b>	<b>(3)</b>
<b>Profit attributable to owners of parent</b>	<b>536</b>	<b>544</b>

**(3) Consolidated Statement of Comprehensive Income**

(Millions of yen)

	<b>Q1 FY2019</b> <b>(October 1, 2018–</b> <b>December 31, 2018)</b>	<b>Q1 FY2018</b> <b>(October 1, 2017–</b> <b>December 31, 2017)</b>
<b>Profit</b>	<b>269</b>	<b>540</b>
Other comprehensive income		
Valuation difference on available-for-sale securities	(696)	70
Foreign currency translation adjustments	(27)	22
Remeasurements of defined benefit plans	19	26
<b>Total other comprehensive income</b>	<b>(703)</b>	<b>119</b>
<b>Comprehensive income</b>	<b>(434)</b>	<b>660</b>
<b>Comprehensive income attributable to</b>		
Owners of parent	(155)	665
Non-controlling interests	(279)	(5)