



Overview of Financial Results for the 1st Quarter FY2021

CMIC HOLDINGS Co., Ltd.
February 1, 2021

Business segments and group companies

Blue indicates overseas. *indicates affiliated company

Segment	Products and services	CMIC Group companies (as of end of Dec. 2020)
CRO Business	Services related to pharmaceutical development support and analytical chemistry services	CMIC HOLDINGS Co., Ltd. CMIC Co., Ltd. CMIC ShiftZero K.K. CMIC Korea Co., Ltd. CMIC ASIA-PACIFIC, PTE. LTD. CMIC ASIA PACIFIC (MALAYSIA) SDN. BHD. CMIC Asia-Pacific (Hong Kong) Limited CMIC ASIA-PACIFIC (PHILIPPINES), INC. CMIC ASIA-PACIFIC (AUSTRALIA)PTY LTD CMIC ASIA-PACIFIC (THAI LAND) LIMITED CMIC (Beijing) Co., Ltd. CMIC DATA SCIENCE VIETNAM COMPANY LIMITED CMIC Pharma Science Co., Ltd. CMIC, INC.
CDMO Business	Services related to drug formulation development and manufacturing support, from formulation design to investigational new drug manufacturing to commercial production of ethical drugs and nonprescription drugs for pharmaceutical companies	CMIC CMO Co., Ltd. CMIC CMO NISHINE Co., Ltd. CMIC CMO Korea Co., Ltd. CMIC CMO USA Corporation CMIC Bio Co., Ltd.
CSO Business	Services provided to pharma companies related to sales & marketing support	CMIC Ashfield Co., Ltd. McCann MDS Inc.*
Healthcare Business	SMO services, healthcare services related to treating, maintaining, and promoting the health for medical institutions, patients and general consumer, and services related to BPO and human resources	CMIC HOLDINGS Co., Ltd. CMIC HealthCare Institute Co., Ltd. CMIC Career Co., Ltd. CMIC Well Co., Ltd.
IPM Business	Provision of new business solution to pharmaceutical companies that combines the system to support all value chains and manufacturing authorization and other licenses (intellectual properties) held by CMIC Group	CMIC HOLDINGS Co., Ltd. CMIC CMO Co., Ltd. OrphanPacific, Inc.

*The corporate name of CMIC Career Co., Ltd. was changed to CMIC Solutions Co.,LTD. as of Jan. 1, 2021.

Main initiatives of the current term



✓ Focus activities "2019-2021 Mid-term Plan"

- ◆ In addition to the PVC model, we will accelerate the IPM solution business that combines the marketing authorization licenses
- ◆ Strengthening Area Competitiveness and promoting Globalization
- ◆ Creation of healthcare business

✓ "Healthcare Revolution 2.0" started from July 2020

- ◆ Transform ourselves from business model centering on pharmaceutical drugs to creation of new healthcare business
- ◆ Create new businesses that will contribute to maintaining and improving personal health
- ◆ Utilize our talents in the healthcare arena

Progress of 1st quarter of FY2021



✓ Contributing to COVID-19 countermeasures

- ◆ Support for COVID-19 vaccination by a local government by using a *harmo*[®]-based vaccine management system
- ◆ Support for clinical trials, post-marketing studies, and clinical research
- ◆ Contract manufacturing of drug for the COVID-19 infection
- ◆ Support for a PCR testing (social testing) project targeting home care providers, etc. from Setagaya Ward

✓ Accelerating & streamlining drug development

- ◆ Started a demonstration experiment of clinical trial using *harmo*[®]
- ◆ Proposing a new clinical trial model for the New Normal (using digital technology)
- ◆ Launched clinical trial support services targeting digital therapeutics
- ◆ Introduced continuous production equipment, which requires no scale-up from IMP production to commercial production, contributing to the acceleration and cost reduction of development (the operation starting in May 2021)

Progress of 1st quarter of FY2021



✓ **Creating business that contributes to maintaining personal health**

- ◆ A *harmo*[®] project was designated by the Tokyo Metropolitan government as “Business to Establish the Next Generation Wellness Solution (a Project to Promote Commercialization).”
- ◆ Has joined the Healthcare Open Innovation program hosted by Kouhoukai Group of International University of Health and Welfare, with the aim of developing pre-symptomatic disease prevention services and creating personalized healthcare services utilizing data.

✓ **Progress of IPM solution**

- ◆ OrphanPacific, Inc. received a manufacturing and marketing approval of *ORLADEYO Capsules 150mg* for the suppression of acute hereditary angioedema (HAE) attacks in Japan (on Jan. 22, 2021)--- a drug that was developed in Japan by BioCryst Pharmaceuticals, Inc. and will be marketed by Torii Pharmaceutical Co.,Ltd.
- ◆ Grifols Therapeutics LLC received a foreign exceptional approval of *Lynspad*[™] for *Intravenous Infusion 1000 mg* in Japan (on Jan. 22, 2021)---where OrphanPacific, Inc. has provided support toward the approval as an appointed marketing authorization holder and will market it.

Progress of 1st quarter of FY2021

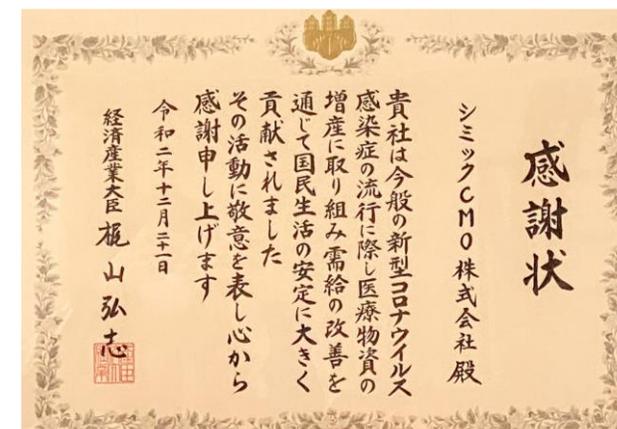
✓ Acquired international standard certification with regard to Information Security Management System (ISMS)

- ◆ Obtained the ISMS-related international standard certification “JIS Q 27001:2014(ISO/IEC27001:2013)” in order for us to continue to strengthen information security and operate appropriately.



認証規格	JIS Q 27001:2014(ISO/IEC 27001:2013)
登録番号	JUSE-IR-470
認証取得事業者	シミックホールディングス株式会社 ICT部 シミック株式会社 データサイエンス事業本部 シミック株式会社 PMS事業本部
登録日	2020年11月27日

✓ CMIC CMO Co., Ltd. received a letter of appreciation from the Ministry of Economy, Trade and Industry as a company that contributed to the increased production of medical supplies in the COVID-19 pandemic.



Consolidated income statement(overview)



	2019/12		2020/12		YoY change	Percent Change
	Amount	Composition ratio	Amount	Composition ratio		
	(¥ millions)	(%)	(¥ millions)	(%)		
Sales	19,800	100.0	18,885	100.0	(915)	(4.6)
Operating income	923	4.7	811	4.3	(111)	(12.1)
Ordinary income	911	4.6	803	4.3	(108)	(11.9)
Profit attributable to owners of parent	481	2.4	561	3.0	80	+ 16.7
Earnings per share	26.63		31.06			

Breakdown of Non-operating income and expenses/Extraordinary income and losses/Income taxes/Profit (loss) attributable to non-controlling interests



(¥ millions)	2019/12	2020/12	(¥ millions)	2019/12	2020/12
Non-operating income	51	125	Extraordinary income	3	115
Interest income	1	3	Gain on sales of non-current assets	3	–
Foreign exchange gains	20	–	Gain on forgiveness of debts	–	115
Share of profit of entities accounted for using equity method	–	27	Extraordinary losses	25	30
Subsidy income	1	56	Loss on retirement of non-current assets	25	–
Other	28	37	Loss on valuation of investment securities	–	30
Non-operating expenses	51	133	Income taxes	416	289
Interest expenses	30	32	Profit (loss) attributable to non-controlling interests	△8	36
Share of loss of entities accounted for using equity method	15	–			
Foreign exchange losses	–	84			
Other	16	16			

Sales & Operating income by segment



		2019/12 Amount (¥ millions)	2020/12 Amount (¥ millions)	Change (¥ millions)	Percent change (%)
CRO Business	Sales	9,193	8,728	(465)	(5.1)
	Operating income	1,541	1,367	(174)	(11.3)
CDMO Business	Sales	5,081	4,913	(168)	(3.3)
	Operating income	(42)	(112)	(70)	–
CSO Business	Sales	2,188	2,053	(135)	(6.2)
	Operating income	233	225	(8)	(3.5)
Healthcare Business	Sales	2,392	2,456	63	+2.6
	Operating income	97	58	(38)	(39.8)
IPM Business	Sales	1,149	924	(224)	(19.6)
	Operating income	51	102	50	+98.2
Adjustments	Sales	(205)	(191)	14	–
	Operating income	(958)	(829)	129	–
Consolidated	Sales	19,800	18,885	(915)	(4.6)
	Operating income	923	811	(111)	(12.1)

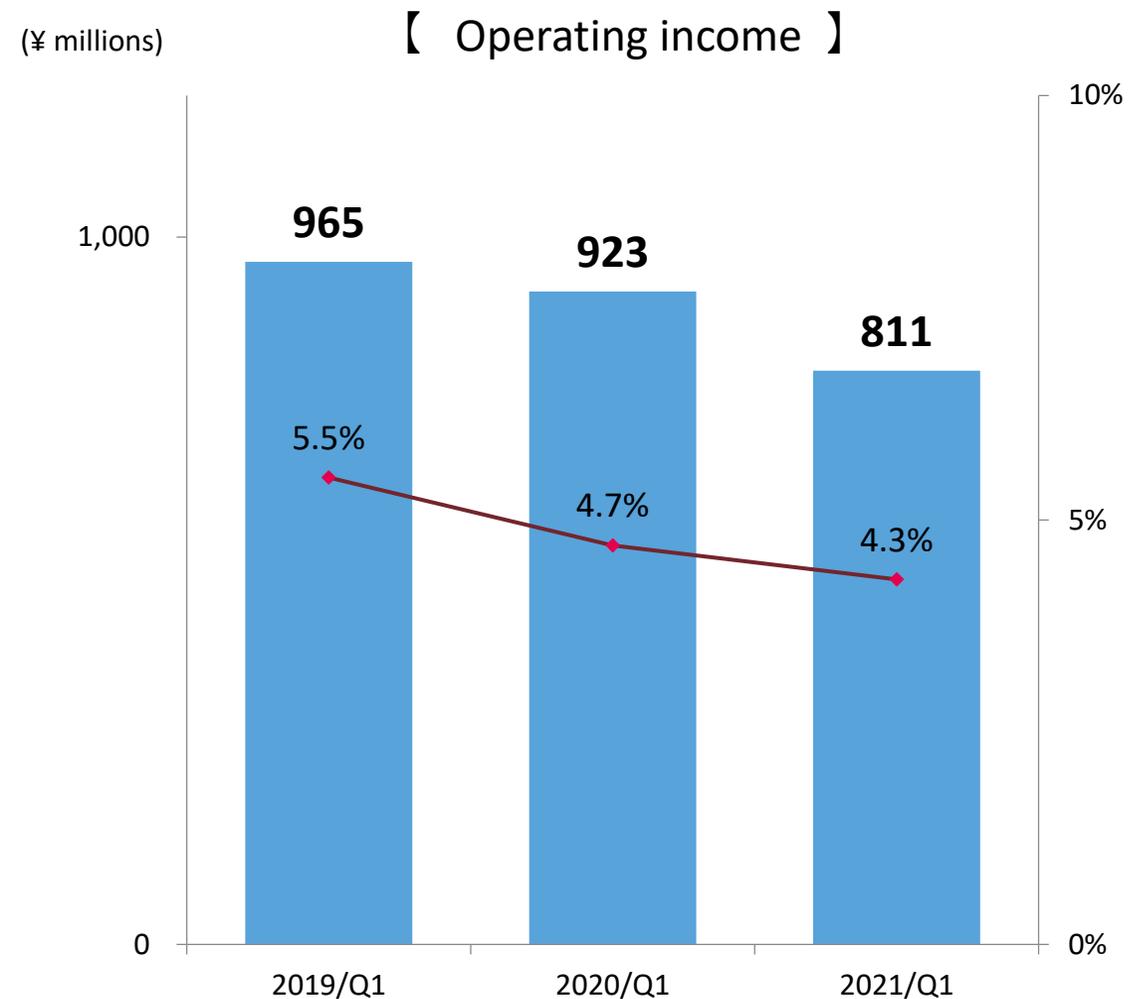
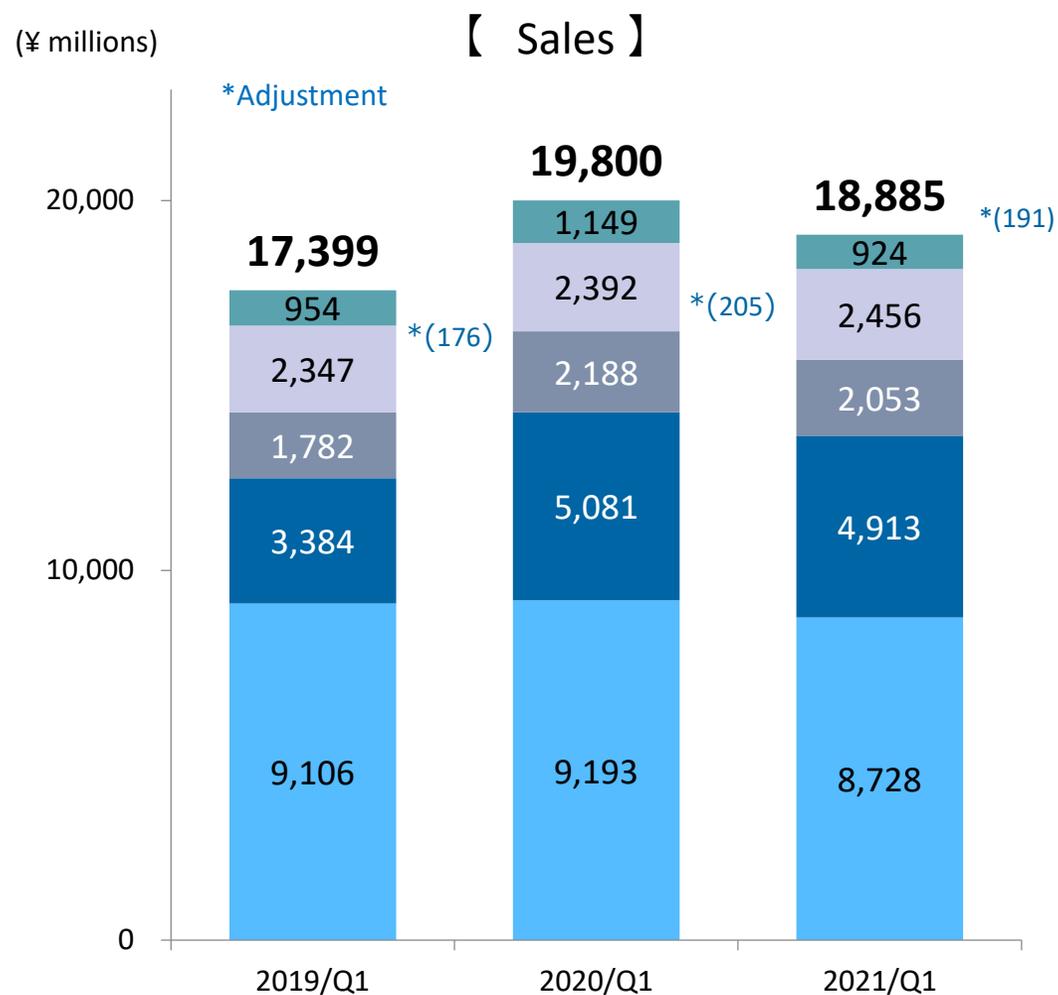
Orders received / Backlog



	2019/12		2020/12			
	Orders received	Backlog	Orders received	Percent Change	Backlog	Percent Change
	(¥ millions)	(¥ millions)	(¥ millions)	(%)	(¥ millions)	(%)
CRO Business	9,187	53,668	9,609	+4.6	57,556	+7.2
CDMO Business	5,062	5,313	4,529	(10.5)	5,056	(4.8)
CSO Business	1,988	3,823	2,047	+2.9	3,126	(18.2)
Healthcare Business	2,984	11,927	3,624	+21.5	13,139	+10.2
Total	19,222	74,733	19,810	+3.1	78,878	+5.5

- The number of orders received increased in all businesses except for CDMO Business.
- Accounts for only the backlog of firm CDMO business orders. There is customer demand for scheduled orders but these are different from firm orders so we have not included these in the backlog.
- Order status is not included for IPM Business because its business conditions are different from those of contract business.

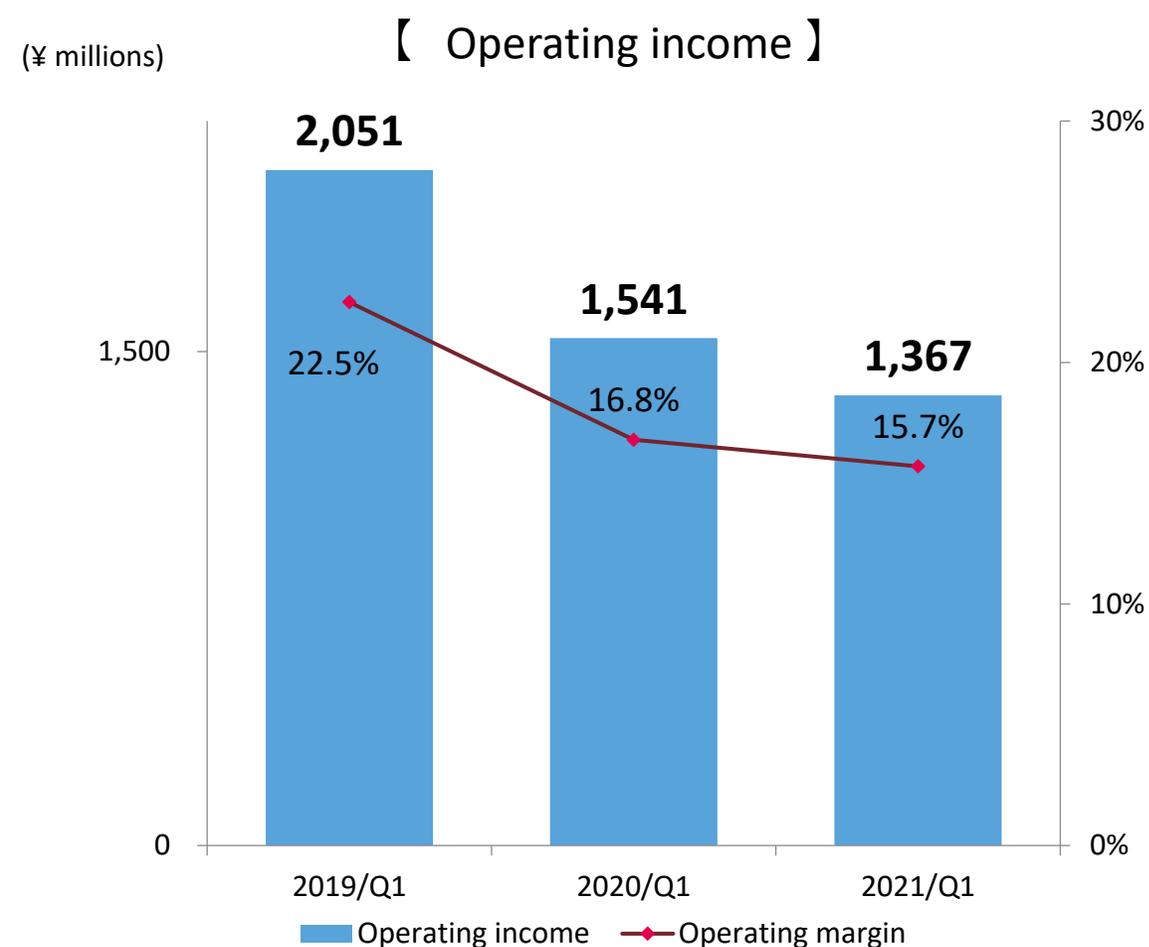
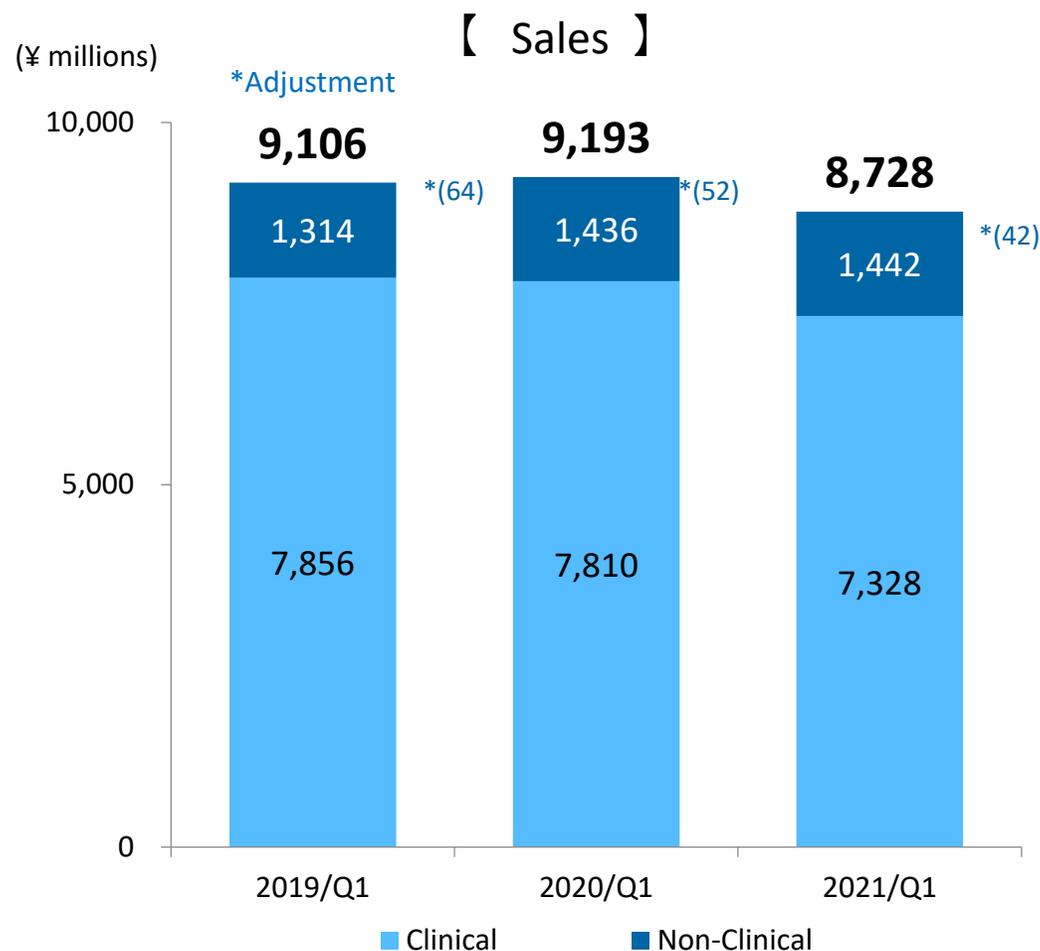
Trends in consolidated sales & operating income



■ CRO Business ■ CDMO Business ■ CSO Business ■ Healthcare Business ■ IPM Business

■ Operating income ◆ Operating margin

Contract Research Organization(CRO) Business



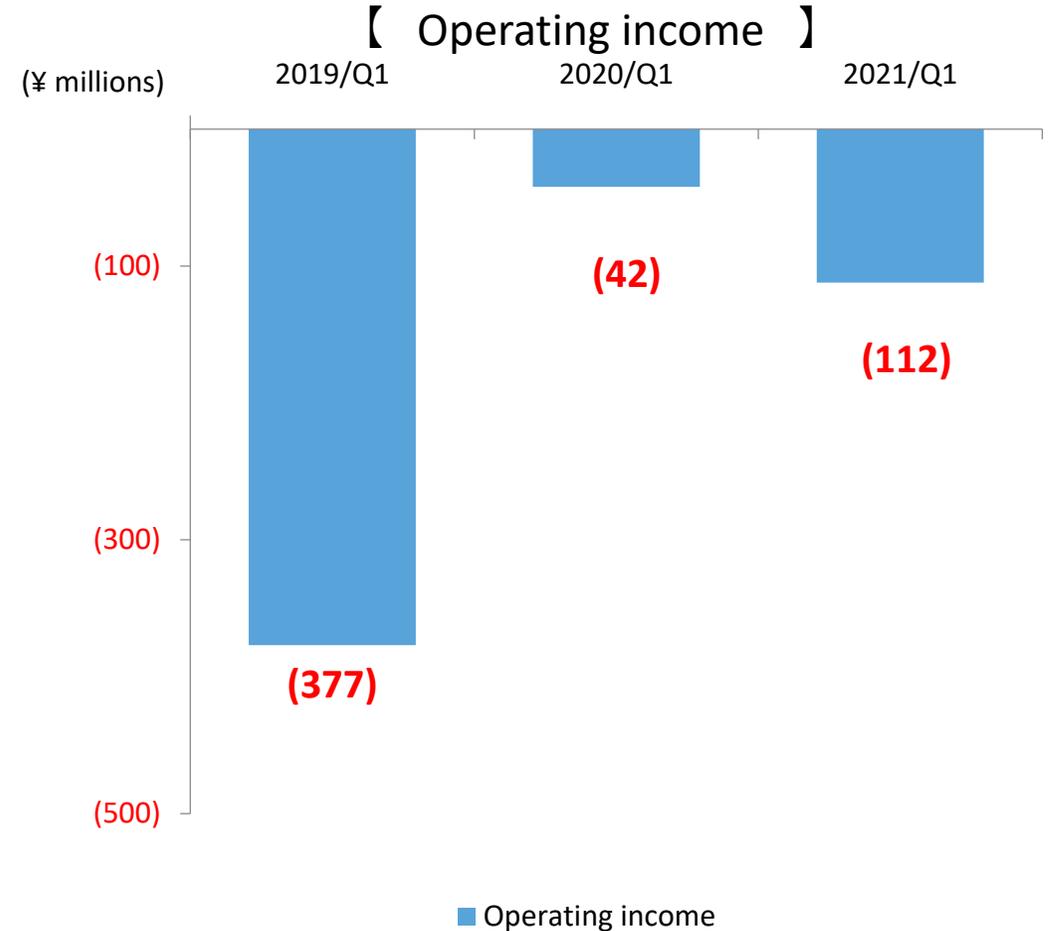
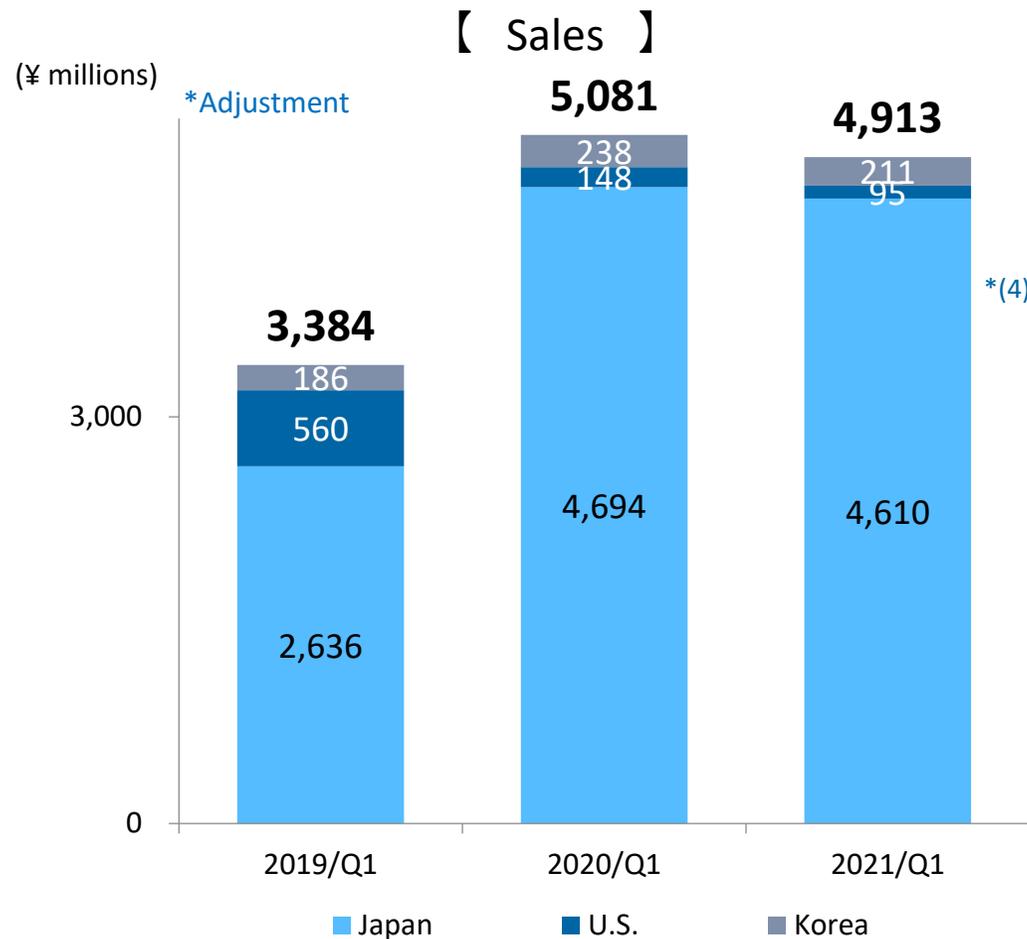
We supported overseas companies entering the Japanese market and non-healthcare companies entering the healthcare sphere and promoted measures to address increasingly sophisticated development needs (biopharmaceuticals, etc.), while helping to maximize the speed of drug development by offering one-stop service from non-clinical to post-marketing.

We are improving the efficiency of clinical trial process by using *harmo*® and proposing a new clinical trial model.

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 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.

Contract Development Manufacturing Organization (CDMO) Business



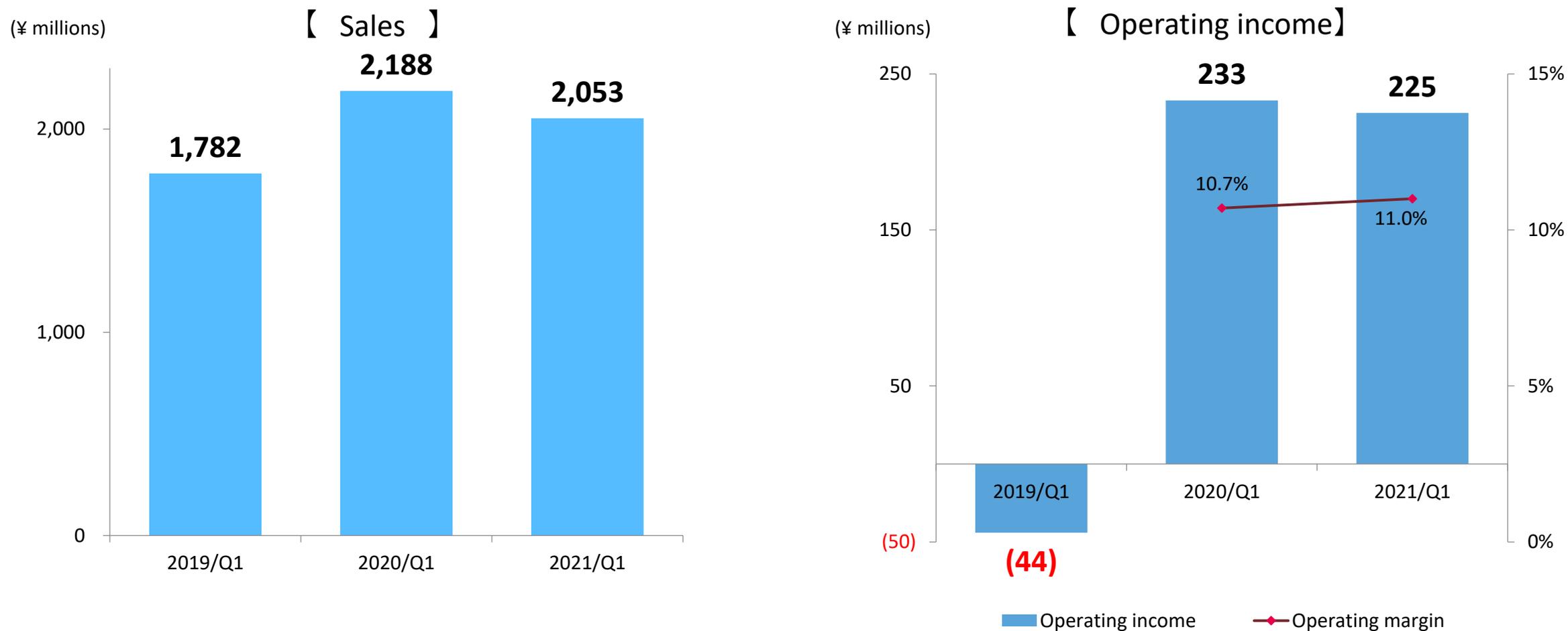
We are further improving technical capabilities and quality, developing a low-cost production structure, and enhancing competitiveness through strategic capital investment as a global pharmaceutical drug manufacturing platform that includes formulation design, investigational new drug manufacturing, and commercial production.

We are focusing on a large-scale commercial production project that is scheduled to start production in the fiscal year ending Sept. 30, 2022, the launch of new facility and production line in the United States, and the acquisition of new projects.

Sales were below the same period of the previous year due to a decrease in contracted production volume.

Operating loss was recorded due to the decrease in sales and prior investment costs for the contract manufacturing business of biopharmaceutical APIs.

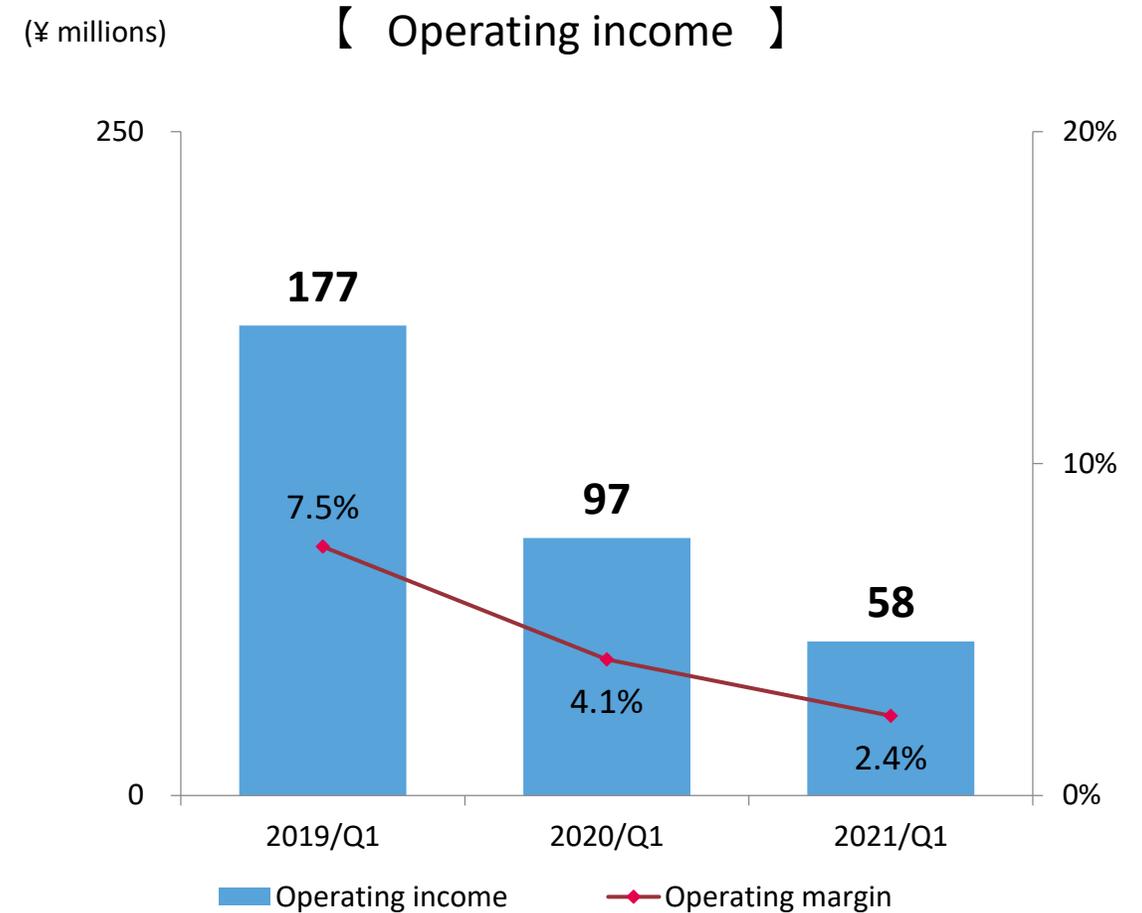
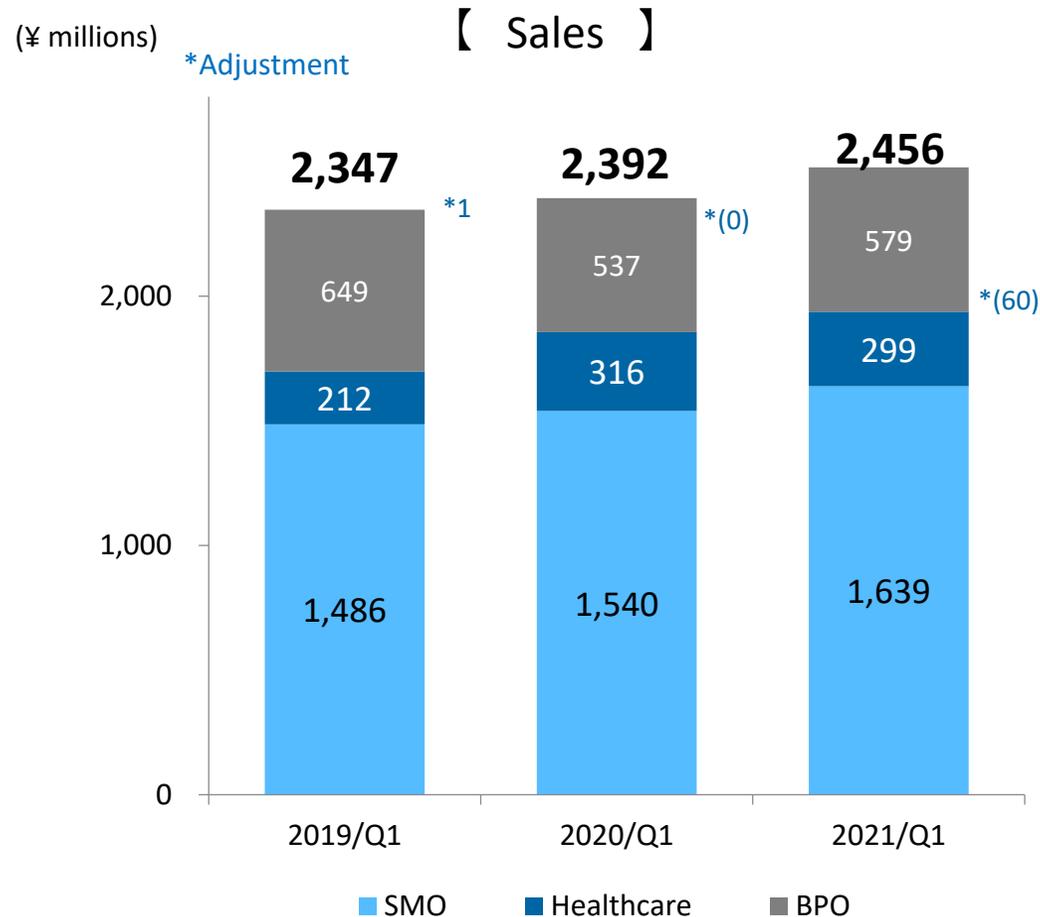
Contract Sales Organization (CSO) Business



- 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.

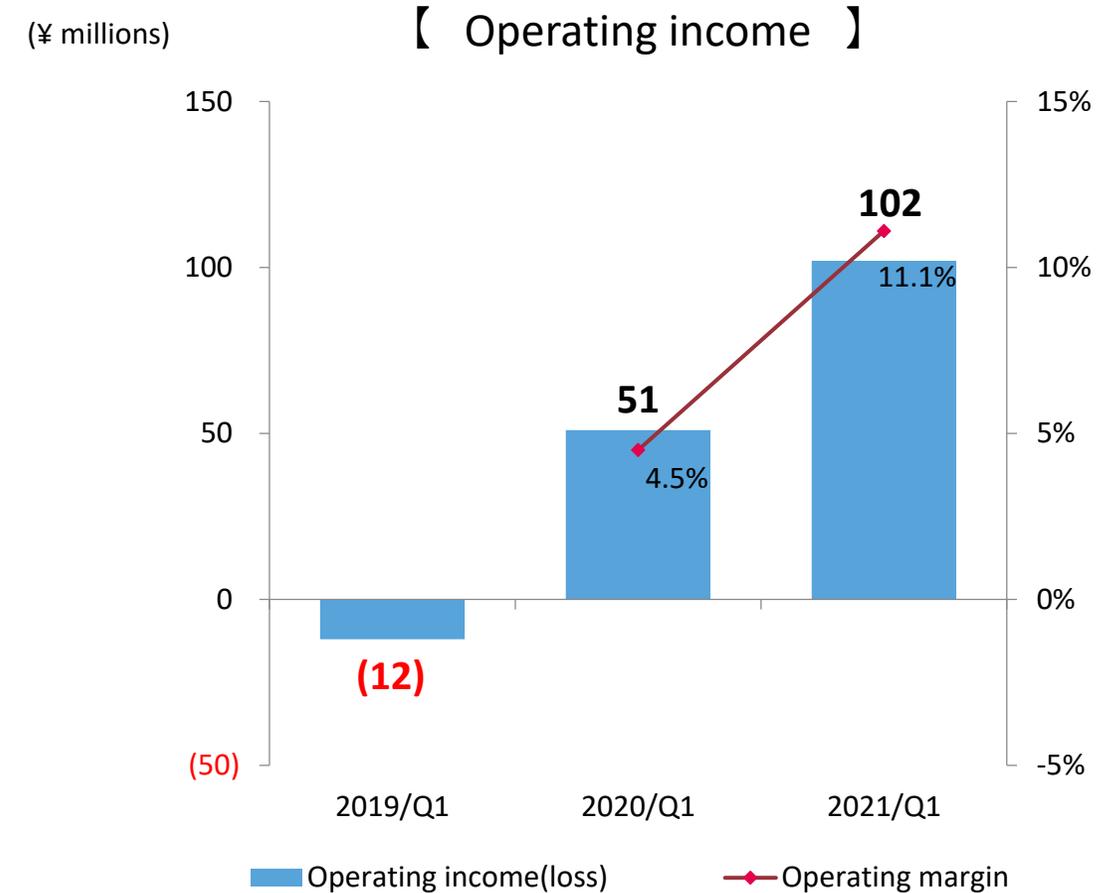
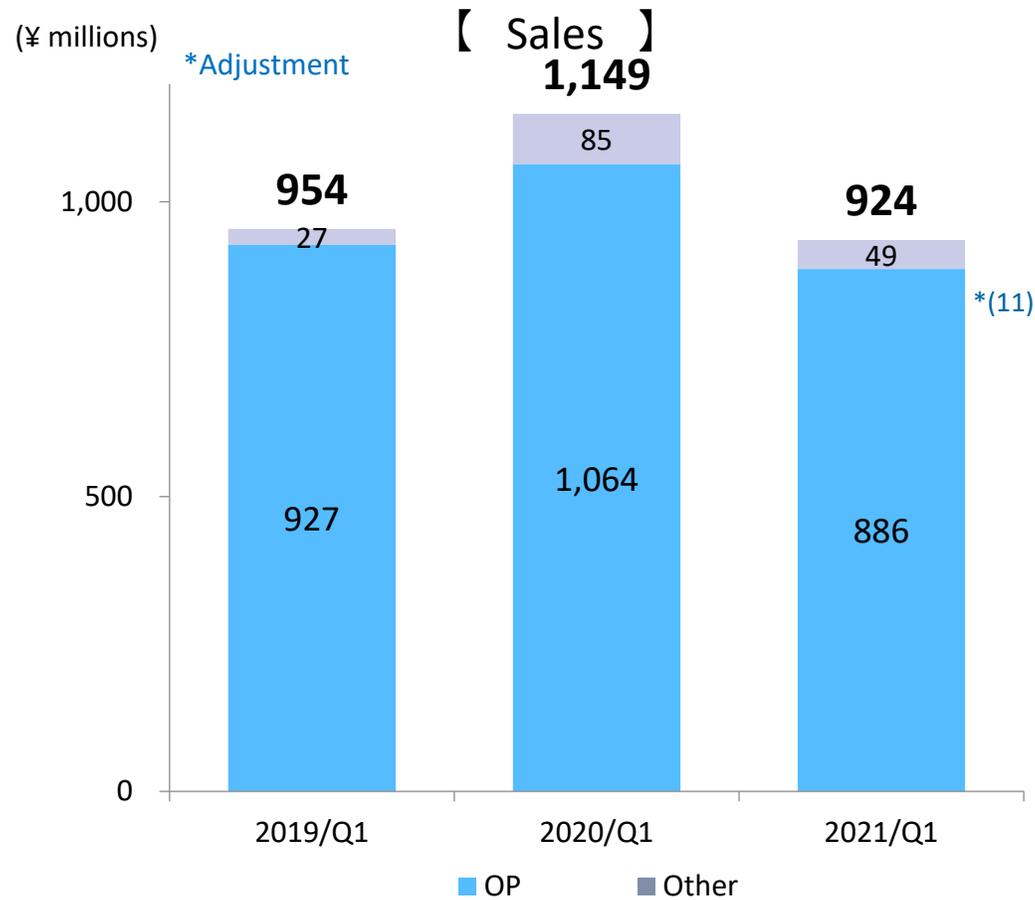
- Sales and operating income were below the same period of the previous year due to a decline in the operation rate in the MR dispatch services.

Healthcare Business



We are expanding our new services by linking SMO operations with BPO services for medical institutions. Also, we are working on the healthcare communication channel *harmo*[®] business and creating new business that contributes to early detection of disease and prevention of disease aggravation. Sales were above the same period of the previous year due to growth in the SMO operations. Operating income was below the same period of the previous year due to prior investments for the creation of new healthcare businesses.

Innovative Pharma Model (IPM) Business

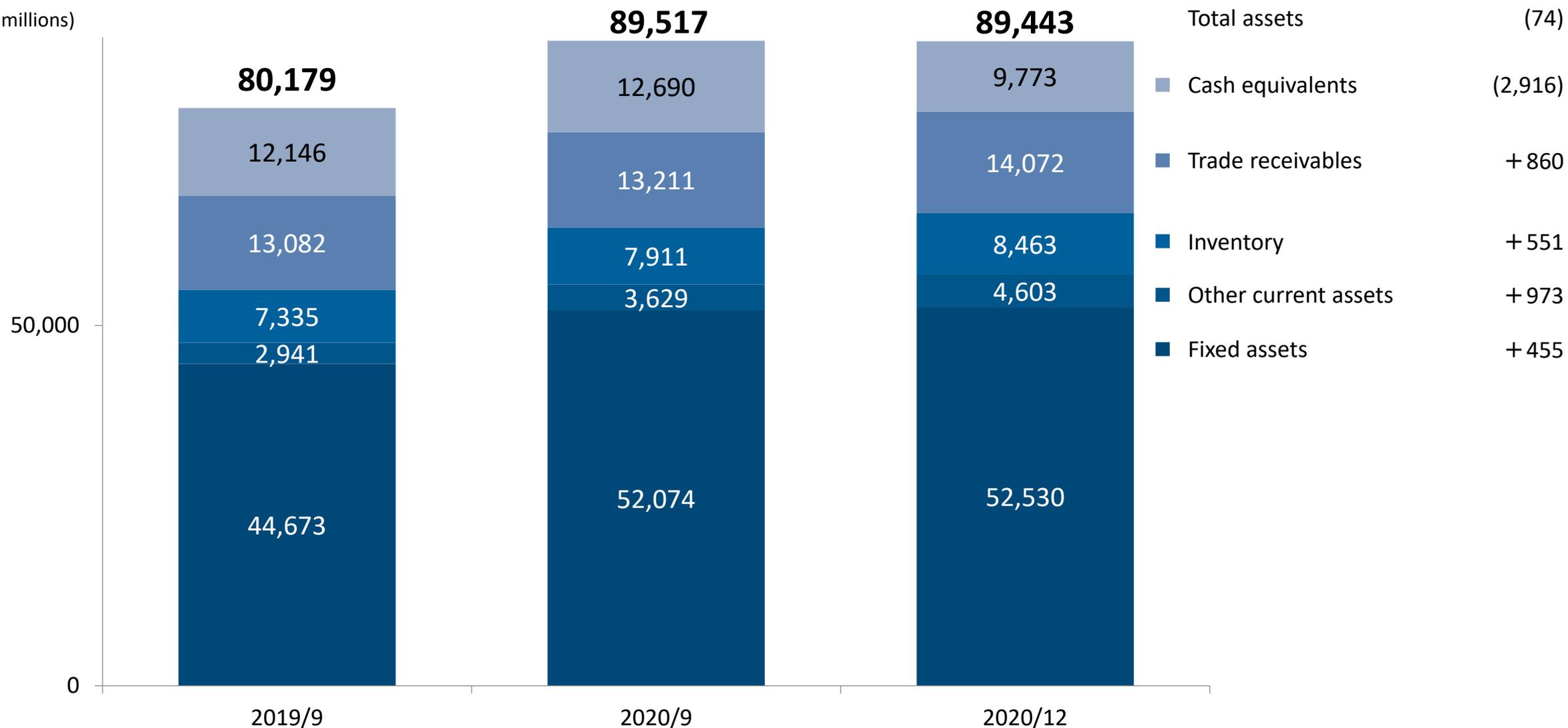


In addition to selling orphan drugs, etc., including products developed in-house, we are supporting foreign pharmaceutical companies entering the Japanese market and providing strategic options to pharmaceutical companies following changes in their business models through the provision of IPM platform. Multiple projects are progressing with increased demand from foreign pharmaceutical companies to use our IPM platform. Sales were below the same period of the previous year due to a decrease in sales volumes of some products. Operating income was above the same period of the previous year due to effects such as the one from reduction in cost.

Balance sheet(assets)



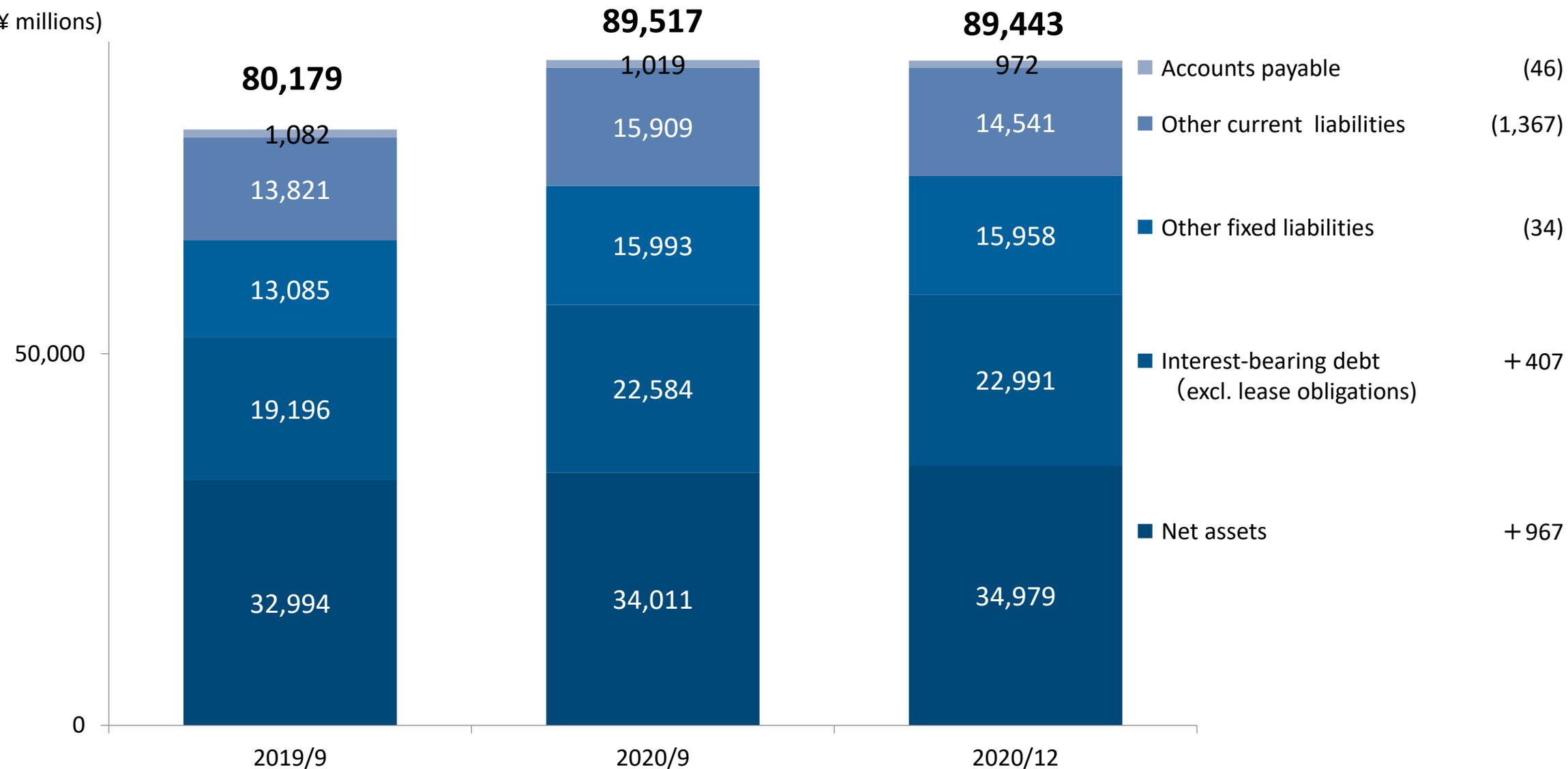
(¥ millions)



Balance sheet (liabilities and net assets)



(¥ millions)





Impacts of the third wave of COVID-19 infection and the state of emergency

- Potential impacts may include delay in collecting data, etc. due to restrictions on visits to medical institutions and a decrease in contracted production volume due to decreased sales volumes of pharmaceuticals.
- With the above, we will strive to enhance order-taking activities for clinical trials and post-marketing surveillance projects related to the COVID-19 infection, expand support services for local governments and medical institutions, utilize our talents in the healthcare arena, and others.

At this point in time, there are no changes to the “consolidated earnings forecast for the fiscal year ended September 30, 2021” announced on November 6, 2020.



Cautionary statement:

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