



Overview of Financial Results for FY2021 3rd Quarter

CMIC HOLDINGS Co., Ltd.
July 30, 2021

Business segments and group companies

- Blue indicates overseas group companies.



Segment	Products and services	CMIC Group companies (as of end of June 2021)
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 ASIA-PACIFIC (VIETNAM) 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.
Healthcare Business	SMO (Site Management Organization) and healthcare services related to treating and maintaining and promoting the health for medical institutions, patients, and general consumers, as well as services related to BPO (Business Process Outsourcing) and human resources	CMIC HOLDINGS Co., Ltd. CMIC HealthCare Institute Co., Ltd. CMIC Solutions Co., Ltd. CMIC Well Co., Ltd.
IPM Business	Provision of new business solutions to pharmaceutical companies, etc. that combine value chains and marketing authorization licenses (intellectual properties) possessed by our Group	CMIC HOLDINGS Co., Ltd. CMIC CMO Co., Ltd. OrphanPacific, Inc.

Main initiatives in the current term



✓ Focus activities in the "Mid-term Plan (FY2019-2021)"

- ◆ In addition to the PVC model, accelerate the IPM solution business that combines marketing authorization licenses
- ◆ Strengthen area competitiveness and promote globalization
- ◆ Create healthcare business

✓ "Healthcare Revolution 2.0" (since 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 3rd quarter of FY2021



✓ Contributing to COVID-19 countermeasures

- ◆ Full fledged support for COVID-19 vaccination by local governments (mass vaccination, mobile vaccination) and preparation for workplace vaccination program
 - Utilization of the COVID-19 vaccination information management system “harmo[®] vaccine care with corona”
 - Call center (to consult about adverse reactions), human resources support (Physician and nurse reference, admin staff)
- ◆ Commissioned by local governments, including Setagaya Ward (as social testing), to provide PCR testing services targeting nursing care providers, etc.
- ◆ Support for clinical trials/post-marketing studies/clinical research, contract manufacturing of COVID-19 treatment drugs
 - Dedicated transportation service started for COVID-19 study subjects for smooth conduction of clinical trials amid COVID-19 outbreak



*harmo[®]: Healthcare Communication Channel

Progress of 3rd 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).”
- ◆ Have 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.
- ◆ Will launch “MONET LABO—HEALTHCARE,” a medical MaaS (Mobility as a Service) specialized business development program, with MONET Technologies.Inc

*MONET: Jointly established by SoftBank Corp., TOYOTA MOTOR CORPORATION, etc.

Progress of 3rd quarter of FY2021



✓ Accelerating & streamlining drug and device development

- ◆ Proposing a new clinical trial model in the age of the New Normal (using digital technology)
 - A demonstration experiment of clinical trial using harmo[®] is ongoing
 - Launched clinical trial support services targeting digital therapeutics
 - Development support for AI medical device clinical trials
- ◆ Signed a joint research agreement on blood cancer with the National Cancer Center Japan
 - Promoting projects for the use of data on gene mutations in refractory leukemia, etc.
- ◆ Introduced continuous production equipment, which requires no scale-up from IMP production to commercial production, contributing to the acceleration and cost reduction of development (plant operation started in May 2021)

Progress of 3rd quarter of FY2021



✓ Progress of IPM solution

- ◆ OrphanPacific, Inc. 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) (on Jan. 22, 2021; NHI price listing on Apr. 21)--- a drug that was developed in Japan by BioCryst Pharmaceuticals, Inc. and will be marketed by Torii Pharmaceutical Co.,Ltd. from Apr. 23.
- ◆ Grifols Therapeutics LLC received a foreign exceptional approval of *Lynspad™ for Intravenous Infusion 1000 mg* in Japan (on Jan. 22, 2021; NHI price listing on Apr. 21)---in which OrphanPacific, Inc. has provided support toward the approval as an appointed marketing authorization holder, and its sales started on July 27.

Progress of 3rd quarter of FY2021



✓ Change of Executive Management (Apr. 2021)

- ◆ Enhanced the corporate hub function and transferred the Group's back-office operations to a group company to respond to business environment changes in a more agile way
- ◆ Repeal of the executive officer system

✓ Launched Group-wide “Healthcare Professional Certification System”

- ◆ Aimed at developing talents who are capable of responding flexibly to the drastically changing healthcare market
- ◆ Dispatch CMIC Group healthcare professionals to COVID-19 vaccine sites, etc.

Progress of 3rd quarter of FY2021

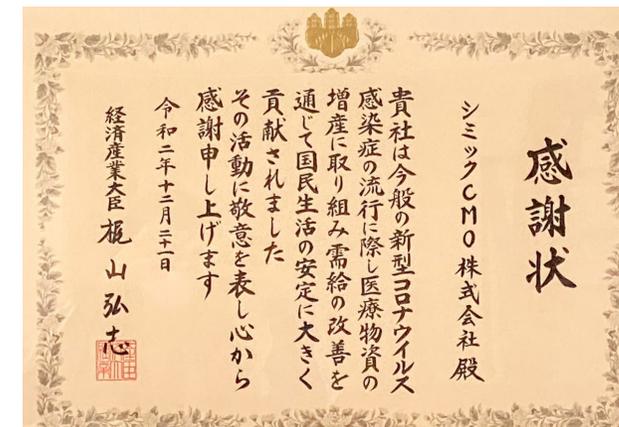
✓ Acquired international standard certification with regard to Information Security Management System (ISMS)

- ◆ 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)



	2020/Q3		2021/Q3		Change	Percent Change
	Amount	Composition ratio	Amount	Composition ratio		
	(¥ millions)	(%)	(¥ millions)	(%)		
Sales	56,736	100.0	59,146	100.0	2,409	+4.2
Operating income	3,137	5.5	3,571	6.0	433	+13.8
Ordinary income	3,486	6.1	3,733	6.3	247	+7.1
Profit attributable to owners of parent	2,373	4.2	1,943	3.3	(429)	(18.1)
Earnings per share	131.26		107.44			

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



(¥ millions)	2020/Q3	2021/Q3	(¥ millions)	2020/Q3	2021/Q3
Non-operating income	519	329	Extraordinary income	46	136
Interest income	3	1	Gain on sales of non-current assets	5	–
Foreign exchange gains	–	146	Gain on Sales of investment securities	10	–
Share of profit of entities accounted for using equity method	401	20	Gain on sales of shares of subsidiaries and associates	30	19
Subsidy income	33	94	Gain on forgiveness of debts	–	117
Other	81	66			
Non-operating expenses	170	166	Extraordinary losses	75	95
Interest expenses	89	99	Loss on retirement of non-current assets	75	56
Foreign exchange losses	45	–	Loss on valuation of investment securities	–	39
Other	35	67			
			Income taxes	877	1,626
			Profit (loss) attributable to non-controlling interests	205	203

Sales & Operating income by segment



		2020/Q3 Amount (¥ millions)	2021/Q3 Amount (¥ millions)	Change (¥ millions)	Percent change (%)
CRO Business	Sales	25,605	25,777	172	+0.7
	Operating income	4,288	3,872	(416)	(9.7)
CDMO Business	Sales	15,199	15,617	418	+2.8
	Operating income	15	163	148	+946.6
CSO Business	Sales	6,516	6,600	83	+1.3
	Operating income	768	788	20	+2.7
Healthcare Business	Sales	7,463	9,323	1,859	+24.9
	Operating income	586	1,142	556	+94.9
IPM Business	Sales	2,564	2,453	(110)	(4.3)
	Operating income	121	152	30	+25.2
Adjustments	Sales	(612)	(625)	(12)	—
	Operating income	(2,642)	(2,548)	94	—
Consolidated	Sales	56,736	59,146	2,409	+4.2
	Operating income	3,137	3,571	433	+13.8

Orders received / Backlog



	2020/Q3		2021/Q3			
	Orders received	Backlog	Orders received	Percent Change	Backlog	Percent Change
	(¥ millions)	(¥ millions)	(¥ millions)	(%)	(¥ millions)	(%)
CRO Business	25,310	53,552	29,068	+14.8	60,115	+12.3
CDMO Business	15,576	5,728	15,586	+0.1	5,461	(4.7)
CSO Business	6,298	3,805	7,813	+24.0	4,345	+14.2
Healthcare Business	7,369	11,458	15,183	+106.0	18,045	+57.5
Total	54,555	74,544	67,651	+24.0	87,968	+18.0

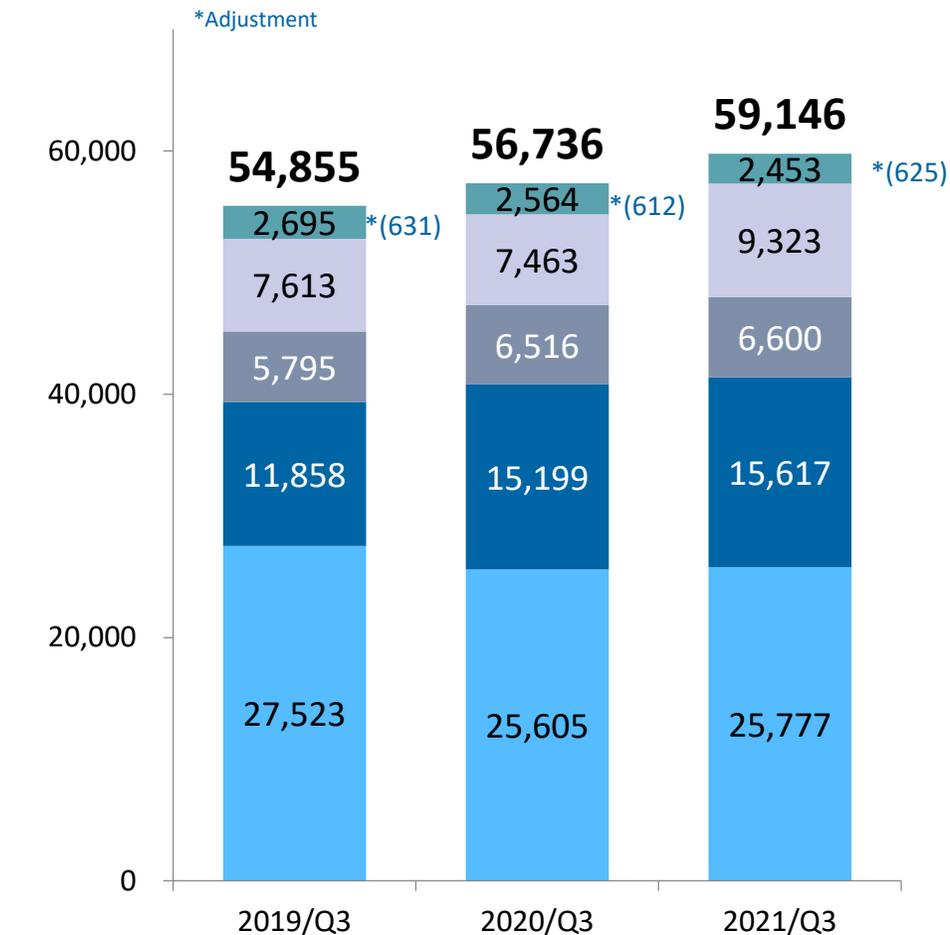
- The orders received increased in segments, including the Healthcare and CSO businesses, which contributed to 24.0% growth compared with the same period of the previous year.
- The backlogs increased by 18.0% from the same period of the previous year.
- Accounts only for the firm business orders in the CDMO business backlog. The annually scheduled orders presented by customers are not equivalent to firm orders so are not included in the backlog.
- The order status excludes the IPM business, for its business conditions are different from those of contract business.

Trends in consolidated sales & operating income



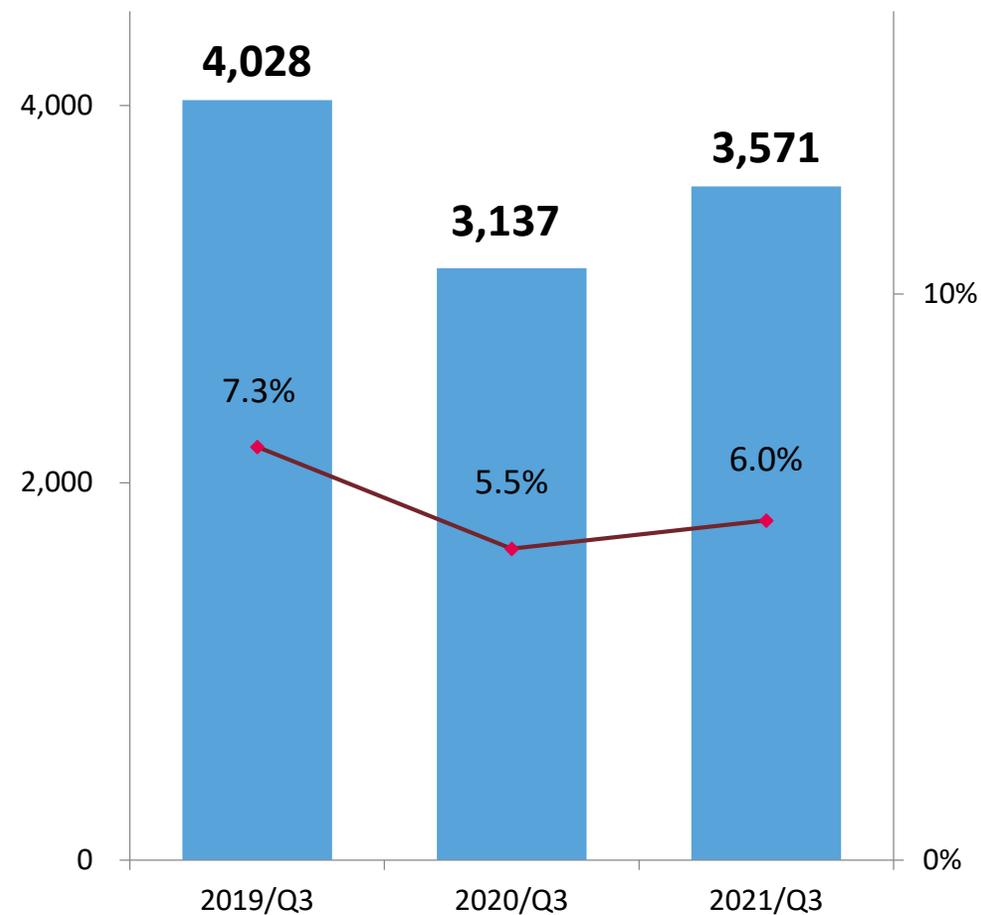
(¥ millions)

【 Sales 】



(¥ millions)

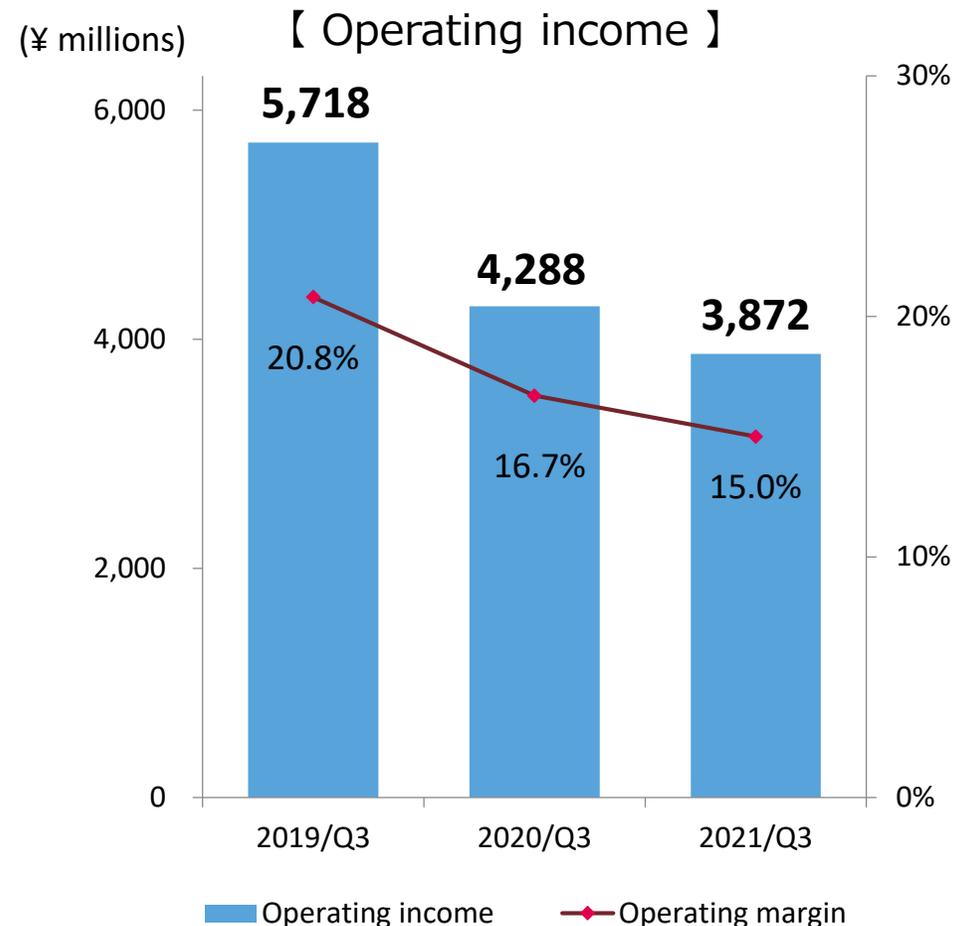
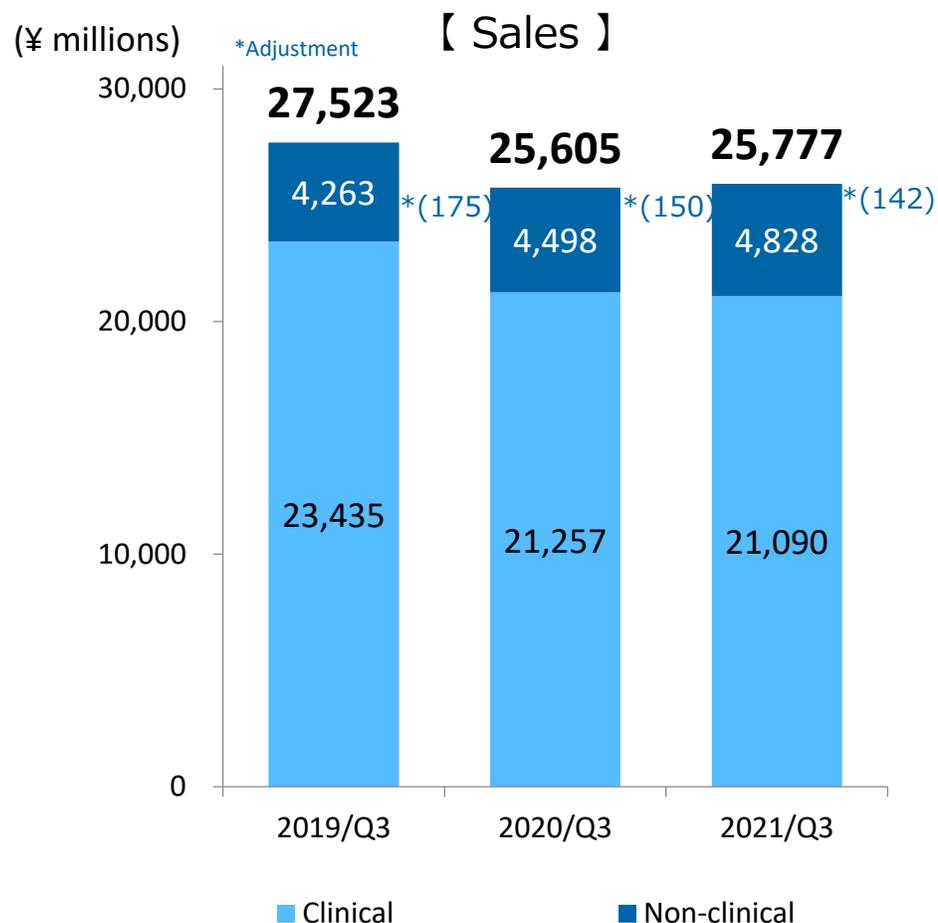
【 Operating income 】



■ CRO business ■ CDMO business ■ CSO business
■ Healthcare business ■ IPM business

■ Operating income ◆ Operating margin

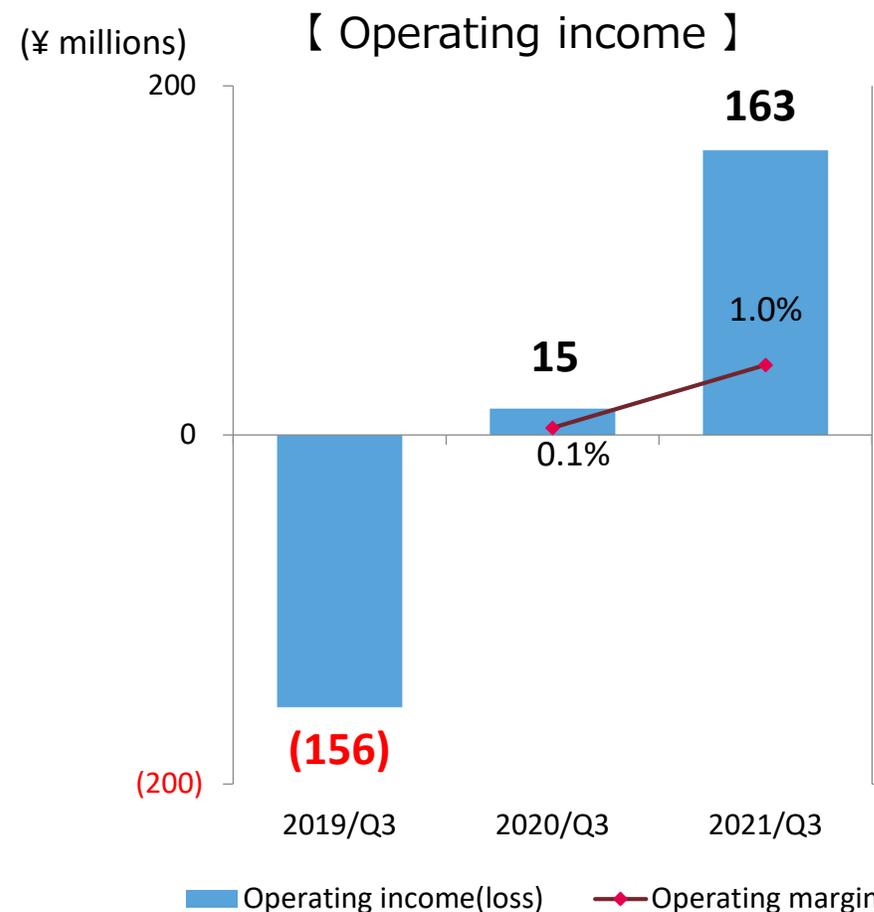
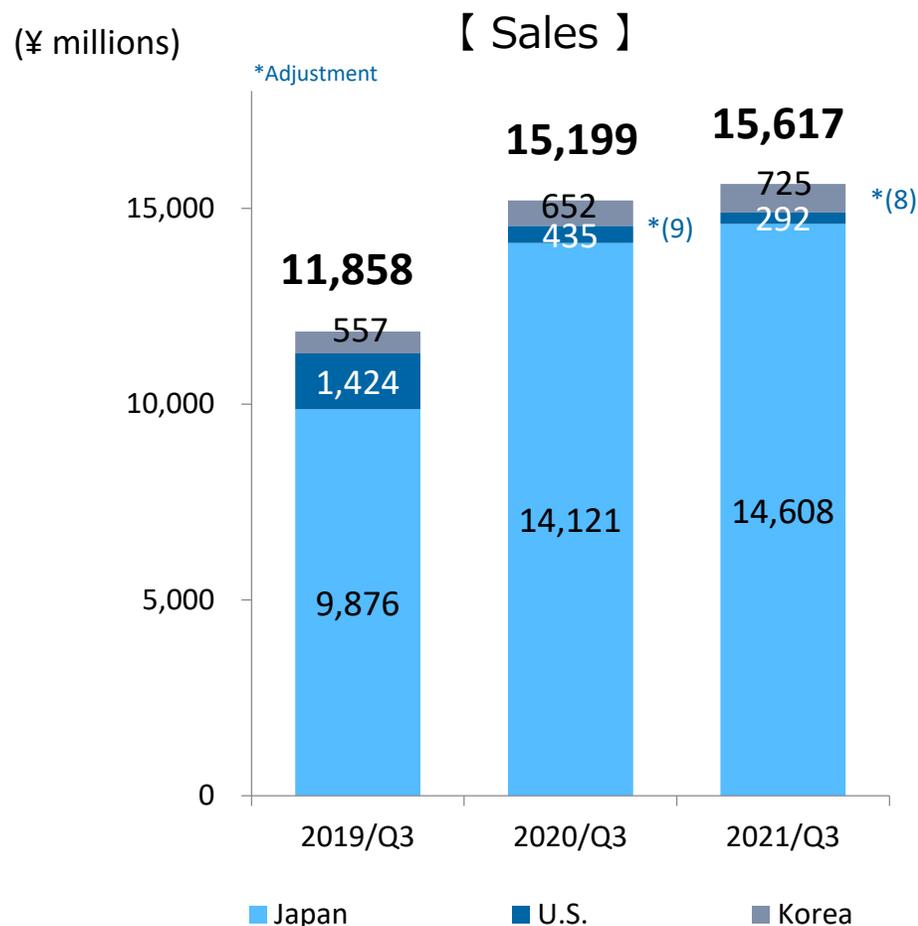
Contract Research Organization (CRO) Business



- Support 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. Propose the improvement of efficiency of clinical trial process by using harmo®, as well as a new clinical trial model.

- 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.

Contract Development Manufacturing Organization (CDMO) Business



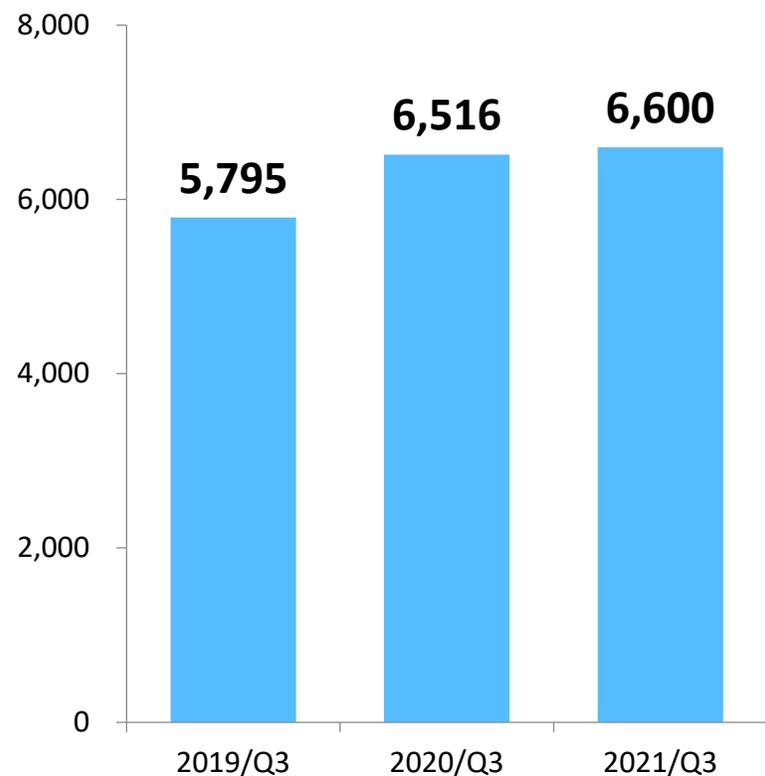
- Improve technical capabilities and quality, develop a low-cost production structure, and enhance competitiveness through strategic capital investment as a global pharmaceutical drug manufacturing platform that includes formulation design, investigational new drug manufacturing, and commercial production
- Focus 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.

Contract Sales Organization (CSO) Business



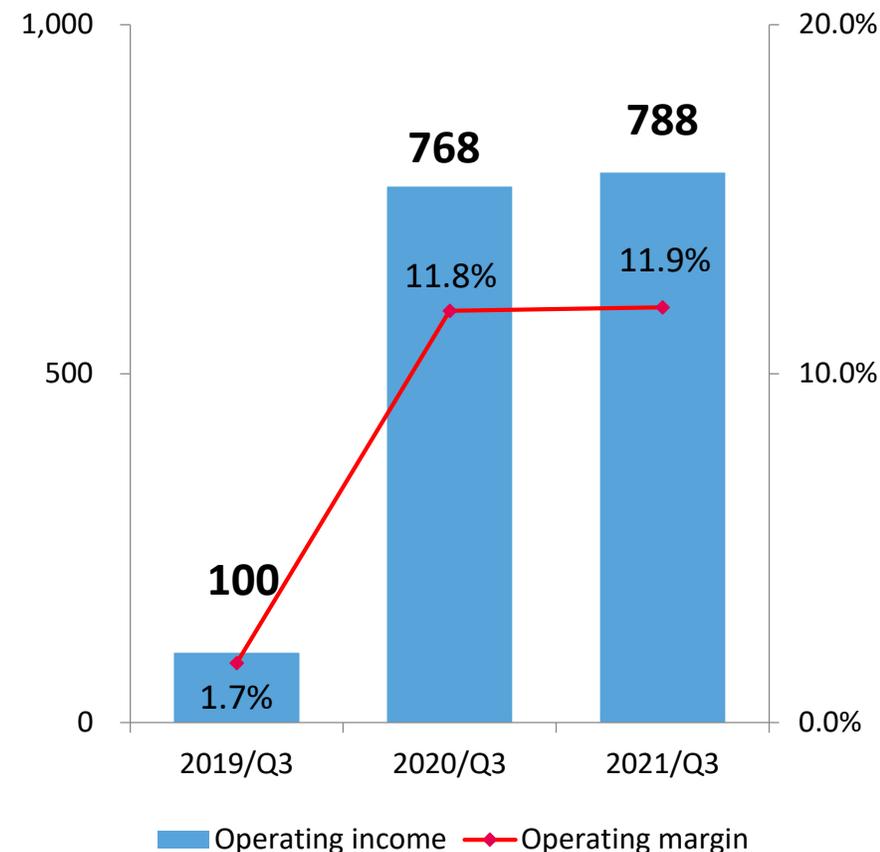
(¥ millions)

【 Sales 】



(¥ millions)

【 Operating income 】



- In addition to the medical representative (MR) dispatch and other related new services, strengthen the sales activities for Medical Affairs-related operations and provide comprehensive solution that combines multiple communication channels and various services.

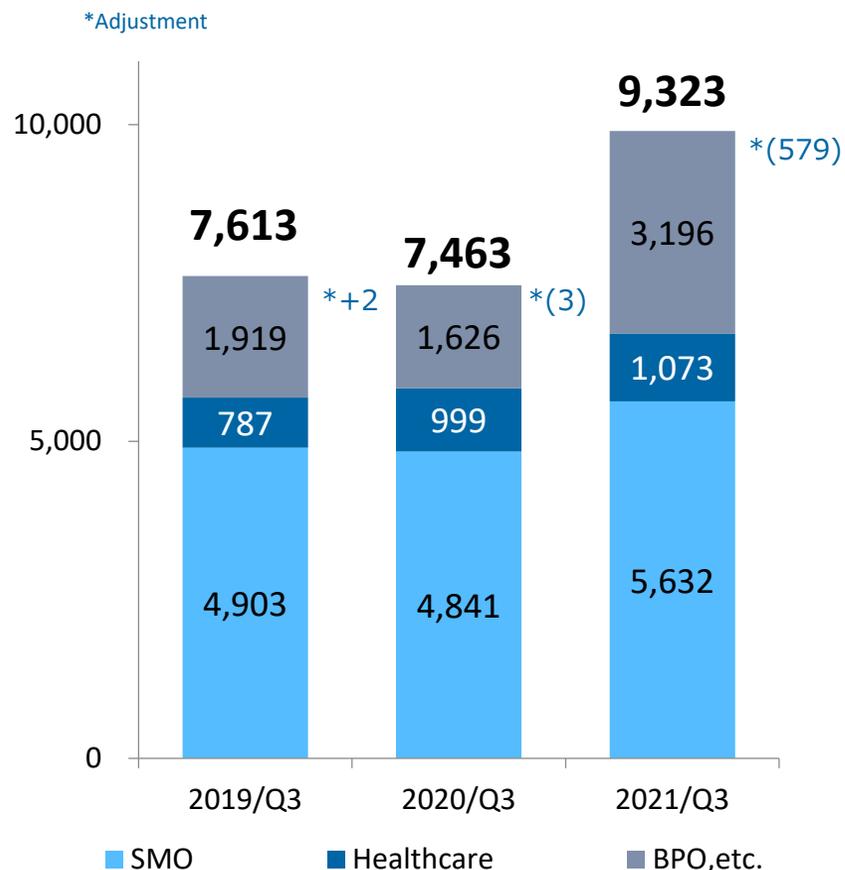
- Sales and operating income exceeded the same period of the previous year, thanks to the acquisition of new MR dispatch service projects.

Healthcare Business



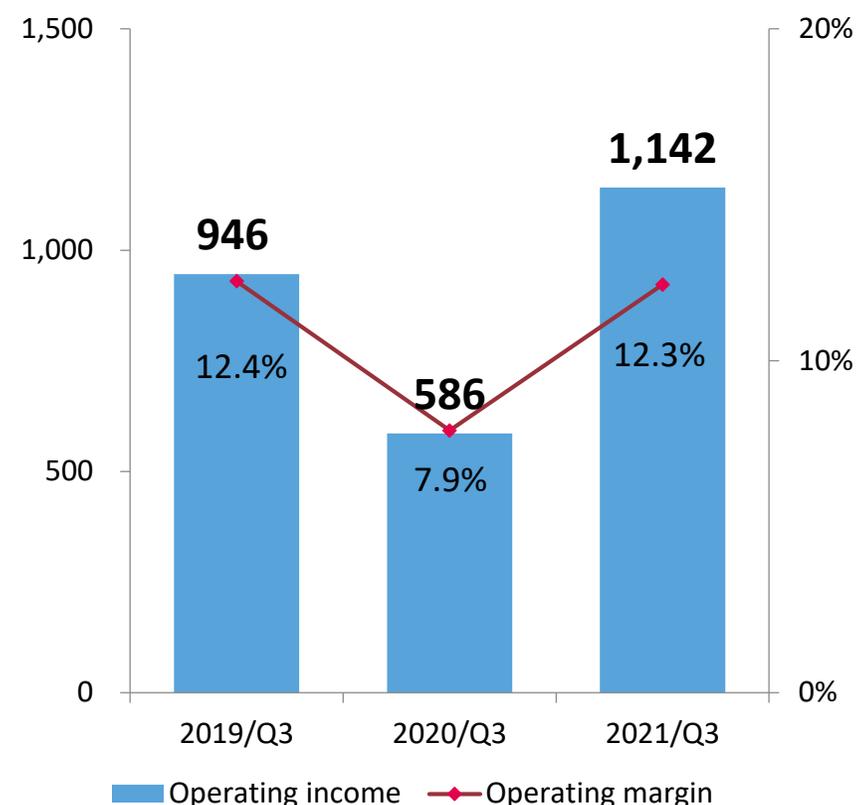
(¥ millions)

【 Sales 】



(¥ millions)

【 Operating income 】



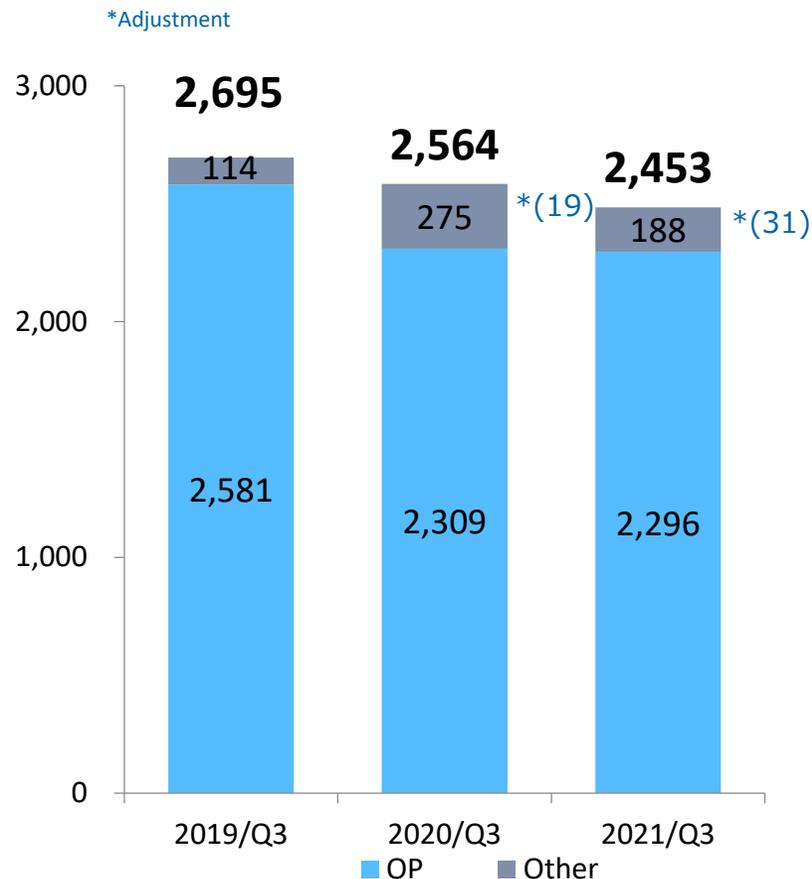
- Focus on supporting the development of effective treatment and preventive measures against COVID-19 infection, as well as supporting the PCR testing and vaccination by local governments.
- Work on the healthcare communication channel harmo® business and create business that contributes to the early detection of disease and prevention of disease aggravation.
- 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.

Innovative Pharma Model (IPM) Business



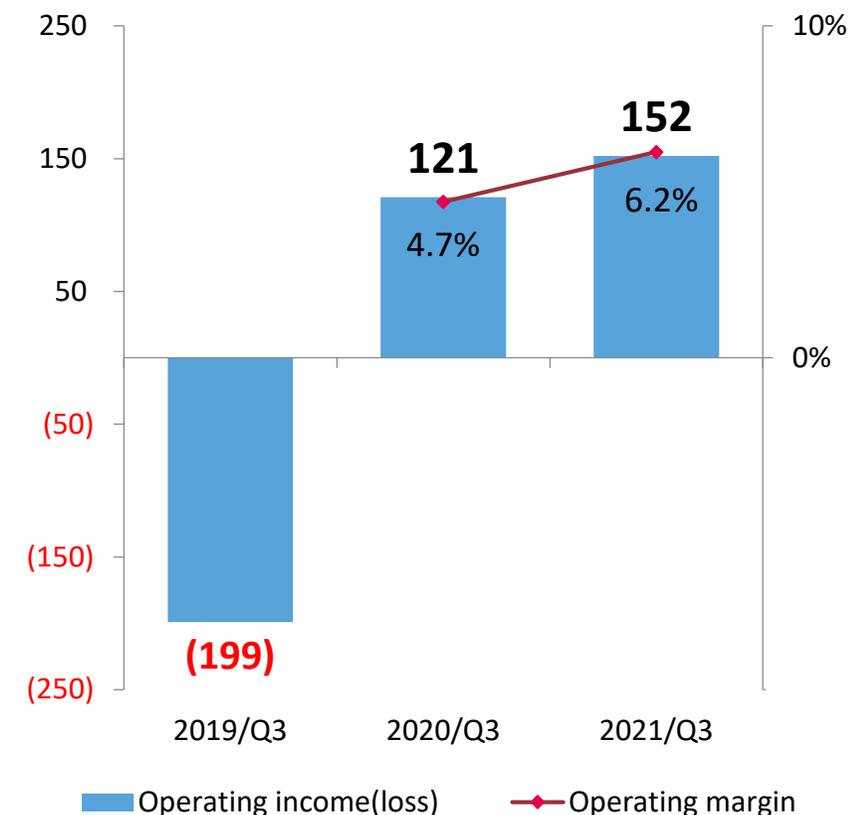
(¥ millions)

【 Sales 】



(¥ millions)

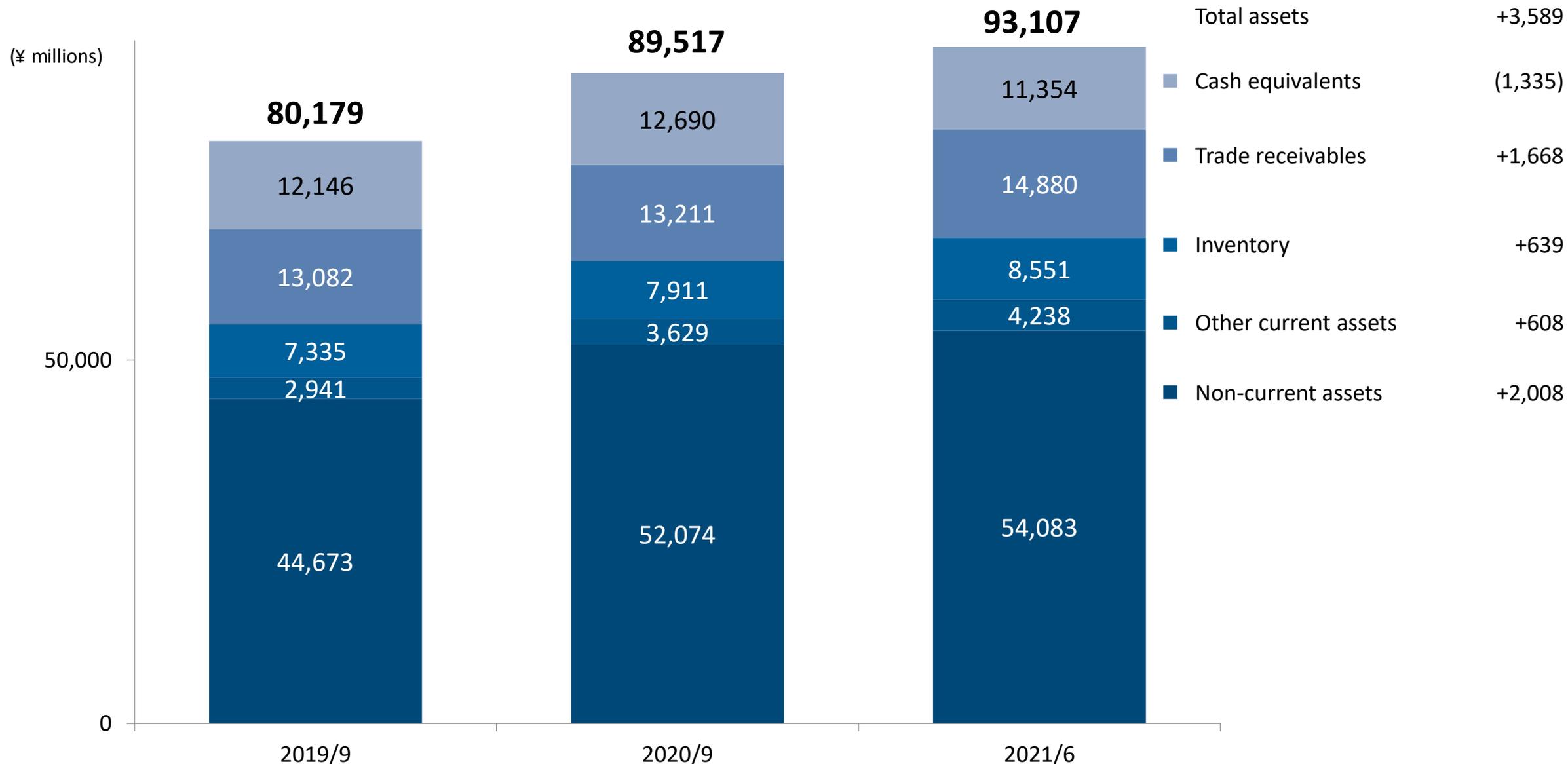
【 Operating income 】



- In addition to selling orphan drugs, etc., including products developed in-house, provide the 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 from foreign pharmaceutical companies to use our IPM platform. In January 2021, two products involved by our IPM business received a manufacturing and marketing approval in Japan.

- Sales were below the same period of the previous year due to a decrease in sales volumes of some products.
- Operating income exceeded the same period of the previous year thanks to cost reduction and other factors

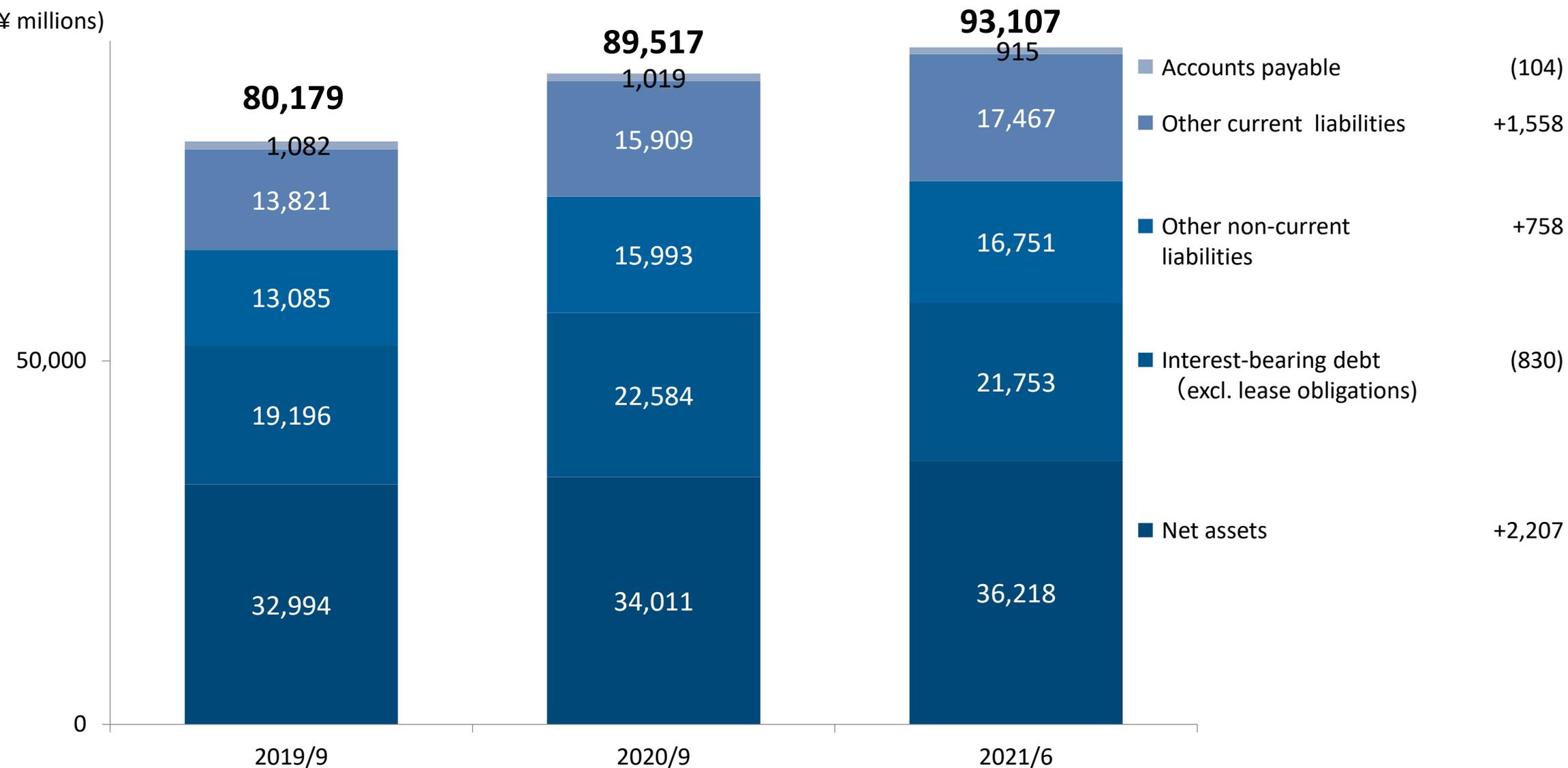
Consolidated balance sheet (assets)



Consolidated balance sheet (liabilities and net assets)



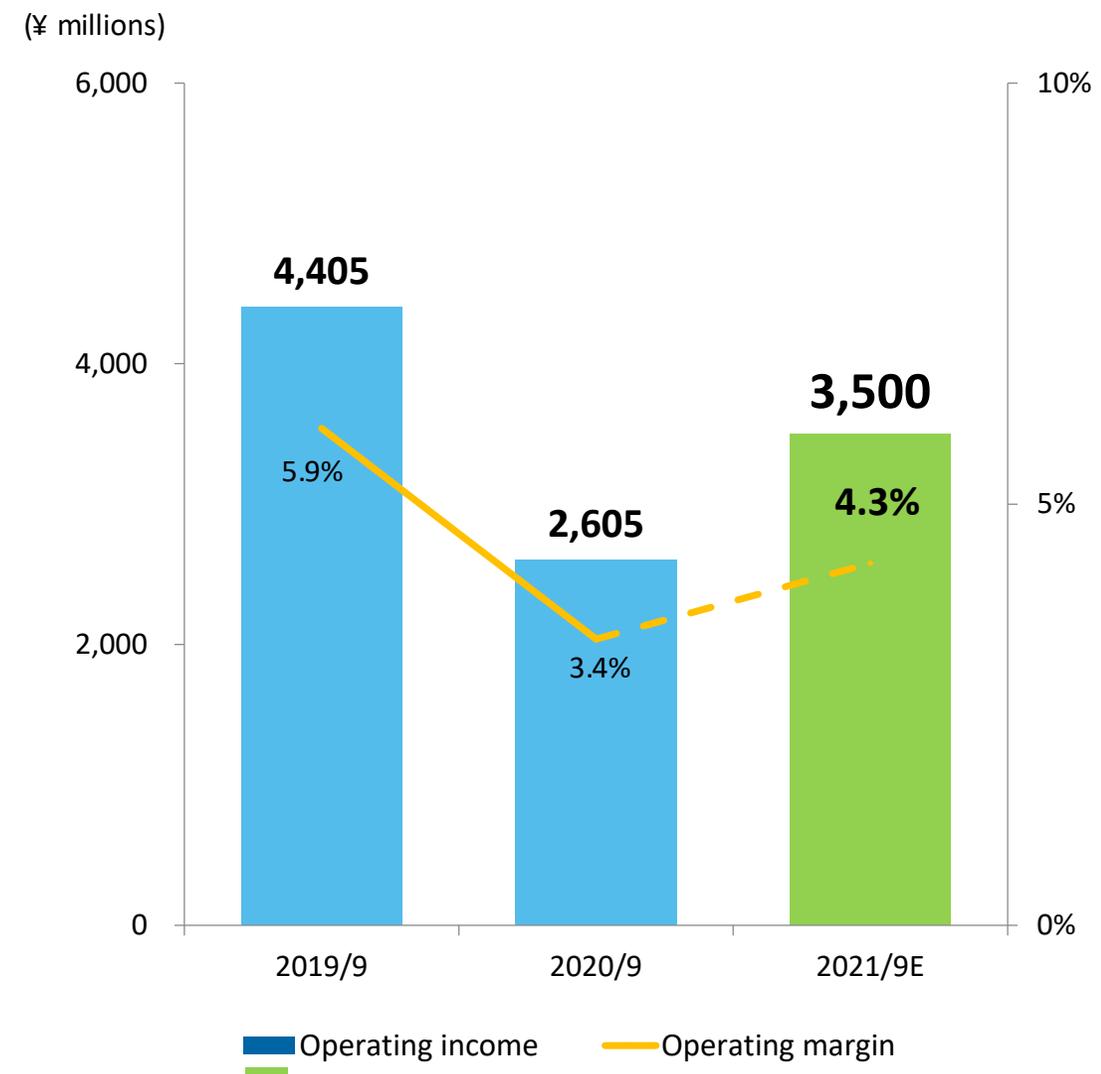
(¥ millions)



Forecast for FY ending Sep. 2021



	2020/9 Actual (¥ millions)	2021/9 Plan (¥ millions)	2021/9 Forecast (¥ millions)	Change from the original plan (%)
Sales	76,098	80,000	82,000	2.5
Operating income	2,605	3,300	3,500	6.1
Ordinary income	2,867	3,100	3,600	16.1
Profit attributable to owners of parent	1,505	1,650	1,700	3.0
Earnings per share	¥ 83.27	¥ 91.21	¥ 93.97	





Cautionary statement:

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