



Overview of Financial Results for FY2021

CMIC HOLDINGS Co., Ltd.
November 5, 2021

Business segments and group companies

- Blue indicates overseas group companies.



Segment	Products and services	CMIC Group companies (as of end of Sep. 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

Achievements in the fiscal year ended in September 2021



✓ 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”
 - Total people registered on harmo vaccine app: 23,000
 - harmo vaccine care with Corona: 1.5 million shots, prescription record users: 420,000
 - 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



Achievements in the fiscal year ended in September 2021



✓ 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
- ◆ Joint development agreement was concluded with ENEOS regarding the heat stress measurement system “lobesense”
- ◆ Activities to support Digital Transformation in Healthcare
“PSP (Patient Support Program) digital platform”

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

Achievements in the fiscal year ended in September 2021



✓ 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)
- ◆ Entered into an agreement with Bayer Yakuhin to improve the efficiency and quality of clinical trials by leveraging digital technology (August 2021)
 - Started using the system that automatically detects information on all drugs contraindicated for coadministration in cardiology clinical trials

Achievements in the fiscal year ended in September 2021



✓ 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.

Achievements in the fiscal year ended in September 2021



✓ **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.

Achievements in the fiscal year ended in September 2021



✓ 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

✓ CDMO 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.



✓ Dr. Emilio Hideyuki Moriguchi received FESCO (Foundation for Social Contribution) 50th Anniversary Award

- * CMIC supports annual travel clinic service for Japanese immigrants in Brazil, which has been provided for over three generations by Dr. Emilio Moriguchi (CMIC’s consultant in Brazil).

✓ CMIC Healthcare Institute received Highest "Eruboshi" certification as a company that promotes women’s participation and advancement in the workplace

Consolidated income statement (overview)



	2020/9		2021/9		Change	Percent Change
	Amount	Composition ratio	Amount	Composition ratio		
	(¥ millions)	(%)	(¥ millions)	(%)		
Net Sales	76,098	100.0	85,788	100.0	+9,690	+12.7
Operating income	2,605	3.4	4,920	5.7	+2,315	+88.8
Ordinary income	2,867	3.8	5,091	5.9	+2,224	+77.6
Profit attributable to owners of parent	1,505	2.0	2,023	2.4	+517	+34.4
Earnings per share	83.27		111.85			

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



(¥ millions)	2020/9	2021/9	(¥ millions)	2020/9	2021/9
Non-operating income	555	399	Extraordinary income	103	714
Interest income	4	2	Gain on sales of non-current assets	7	–
Foreign exchange gains	–	190	Gain on Sales of investment securities	10	577
Share of profit of entities accounted for using equity method	394	20	Gain on sales of shares of subsidiaries and associates	30	19
Subsidy income	43	98	Gain on forgiveness of debts	–	117
Other	113	88	Insurance claim income	54	–
Non-operating expenses	293	228	Extraordinary losses	1,013	2,331
Interest expenses	123	133	Impairment loss	736	2,102
Foreign exchange losses	121	–	Loss on retirement of non-current assets	142	107
Other	48	95	Loss on valuation of investment securities	26	122
			Loss on cancellation of system	108	–
			Income taxes	792	2,397
			Current	1,118	3,947
			Deferred	(325)	(1,550)

Sales & Operating income by segment



		2020/9 Amount (¥ millions)	2021/9 Amount (¥ millions)	Change (¥ millions)	Percent change (%)
CRO Business	Sales	34,242	34,954	+712	+2.1
	Operating income	5,052	4,364	(687)	(13.6)
CDMO Business	Sales	20,832	21,196	+364	+1.7
	Operating income	(412)	(153)	+259	–
CSO Business	Sales	8,626	8,977	+351	+4.1
	Operating income	834	890	+55	+6.7
Healthcare Business	Sales	9,903	17,876	+7,972	+80.5
	Operating income	583	3,590	+3,007	+515.8
IPM Business	Sales	3,395	3,683	+288	+8.5
	Operating income	169	(19)	(188)	–
Adjustments	Sales	(901)	(899)	+1	–
	Operating income	(3,621)	(3,751)	(130)	–
Consolidated	Sales	76,098	85,788	+9,690	+12.7
	Operating income	2,605	4,920	+2,315	+88.8

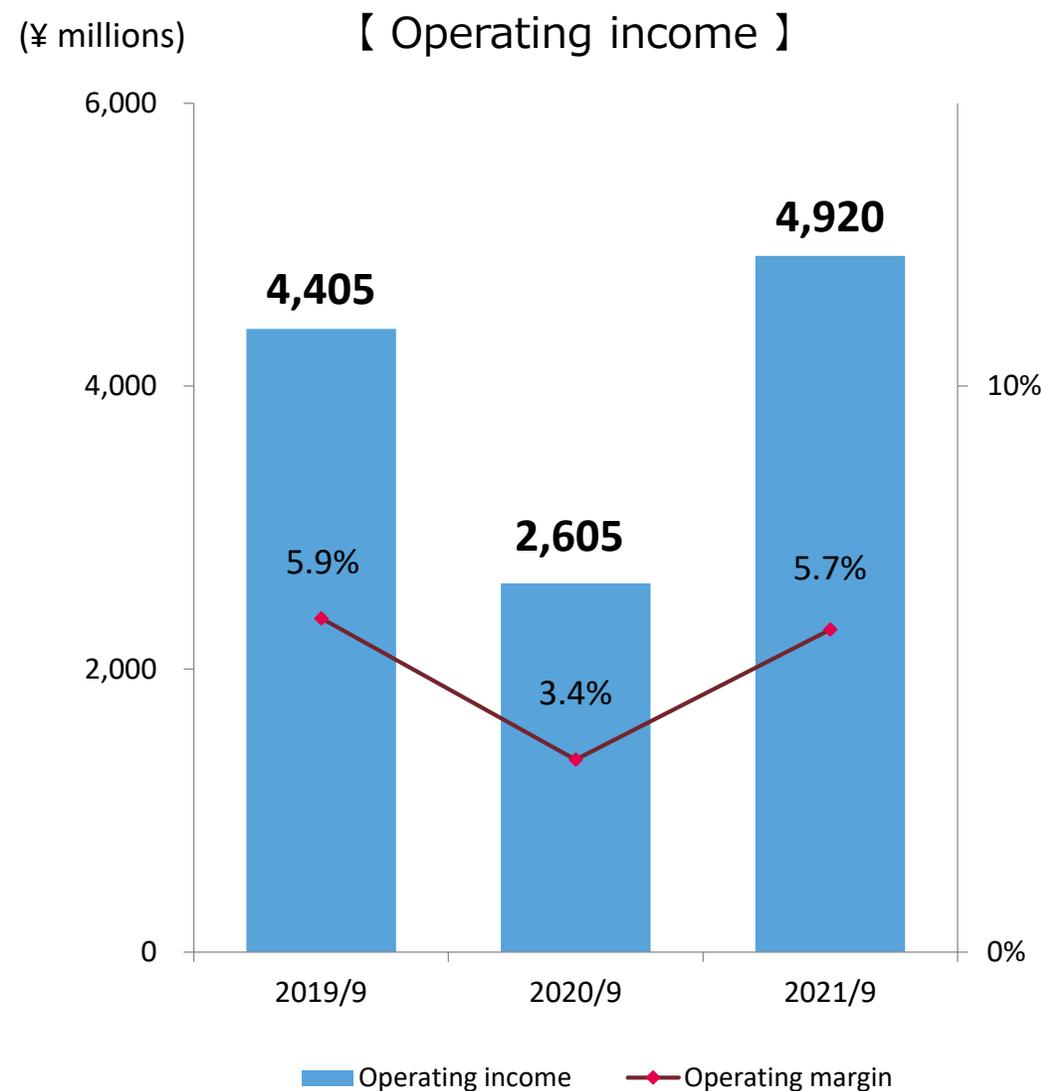
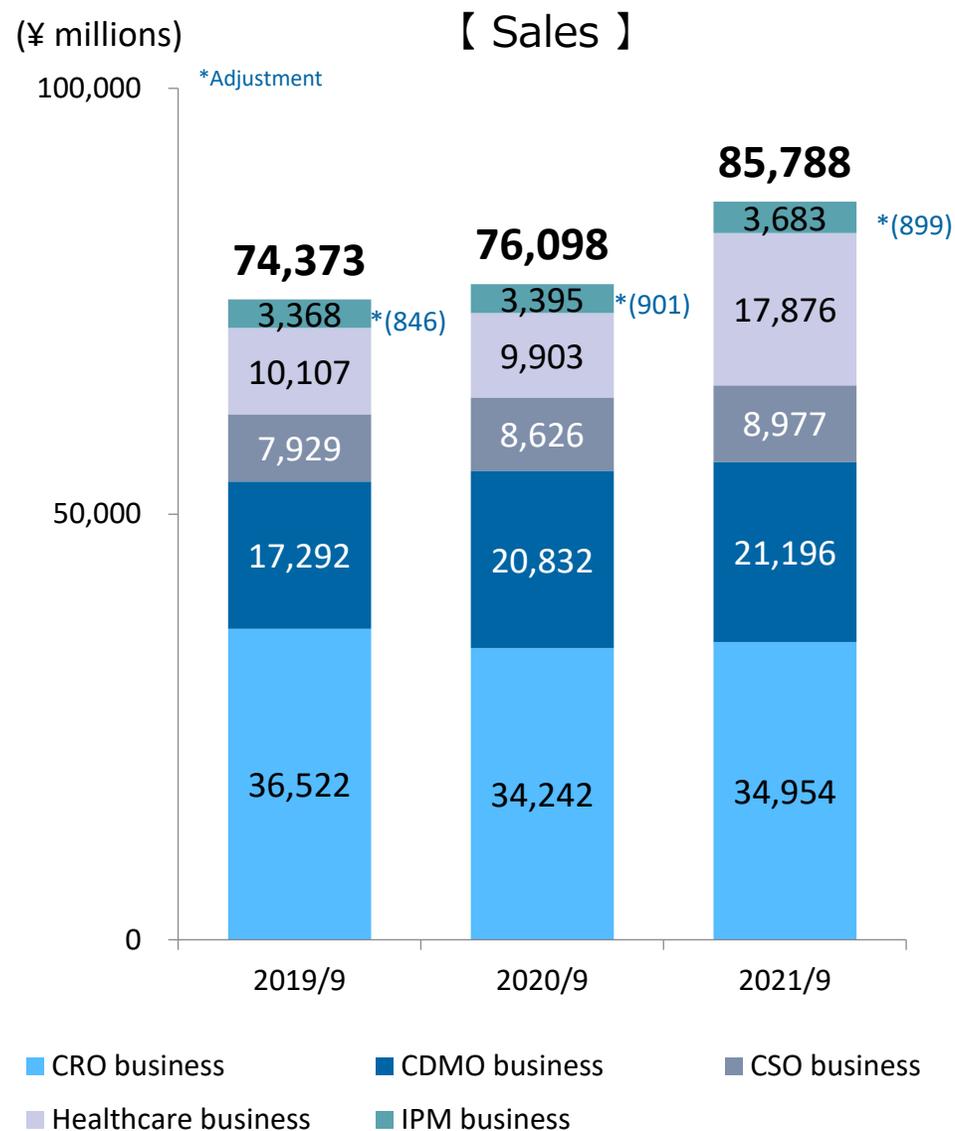
Orders received / Backlog



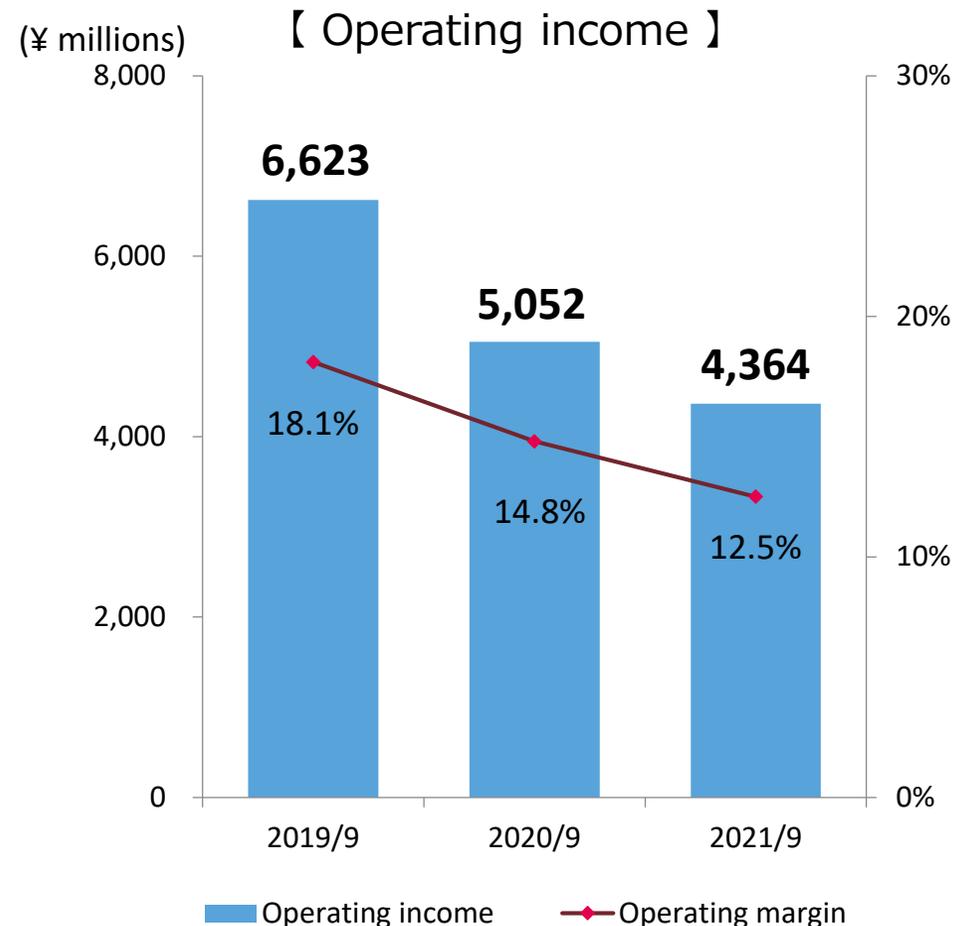
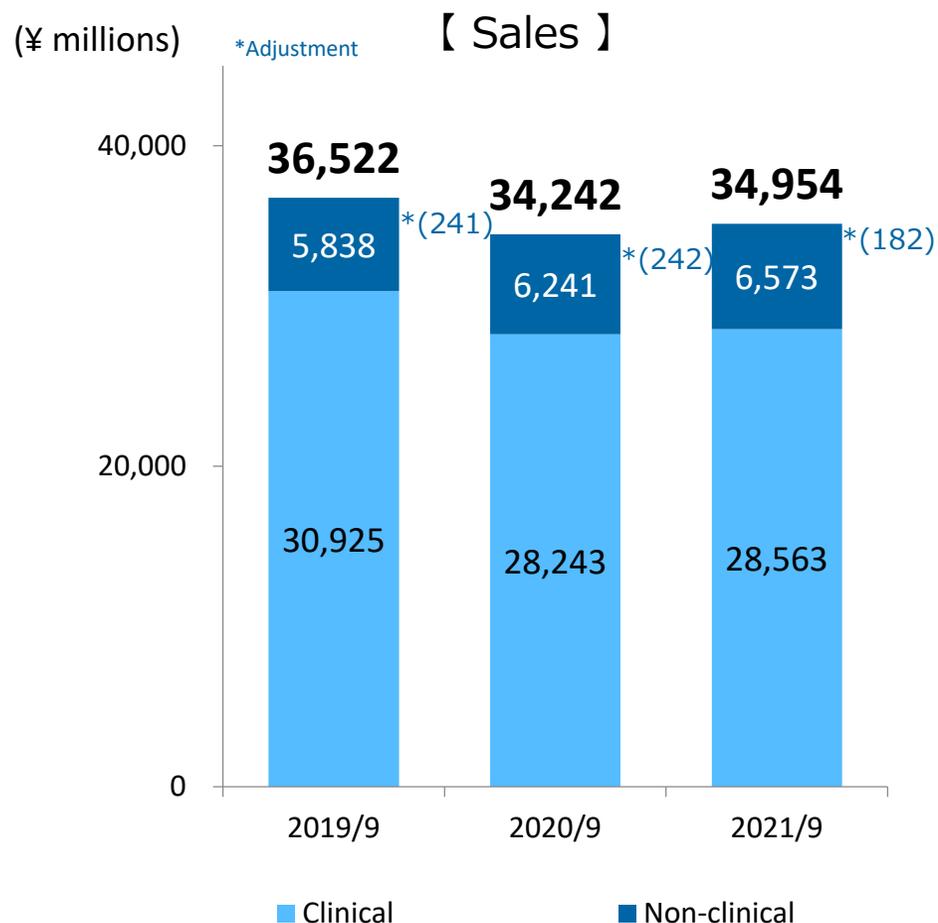
	2020/9		2021/9			
	Orders received	Backlog	Orders received	Percent Change	Backlog	Percent Change
	(¥ millions)	(¥ millions)	(¥ millions)	(%)	(¥ millions)	(%)
CRO Business	36,852	56,608	36,883	+0.1	58,889	+4.0
CDMO Business	20,855	5,412	21,554	+3.4	5,880	+8.6
CSO Business	7,736	3,132	9,413	+21.7	3,568	+13.9
Healthcare Business	10,125	11,873	22,164	+118.9	16,581	+39.7
Total	75,570	77,028	90,015	+19.1	84,920	+10.2

- Both orders received and order backlog exceeded the previous year in all segments.
- The backlogs increased in all the businesses segments.
- 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



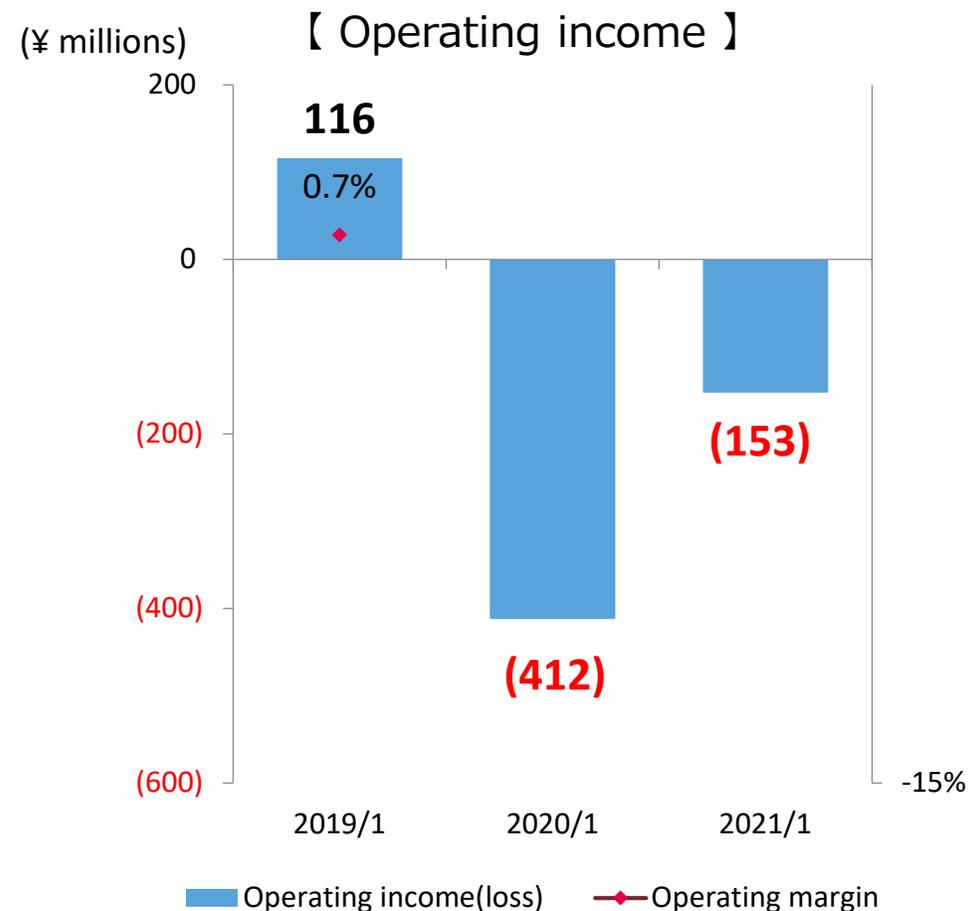
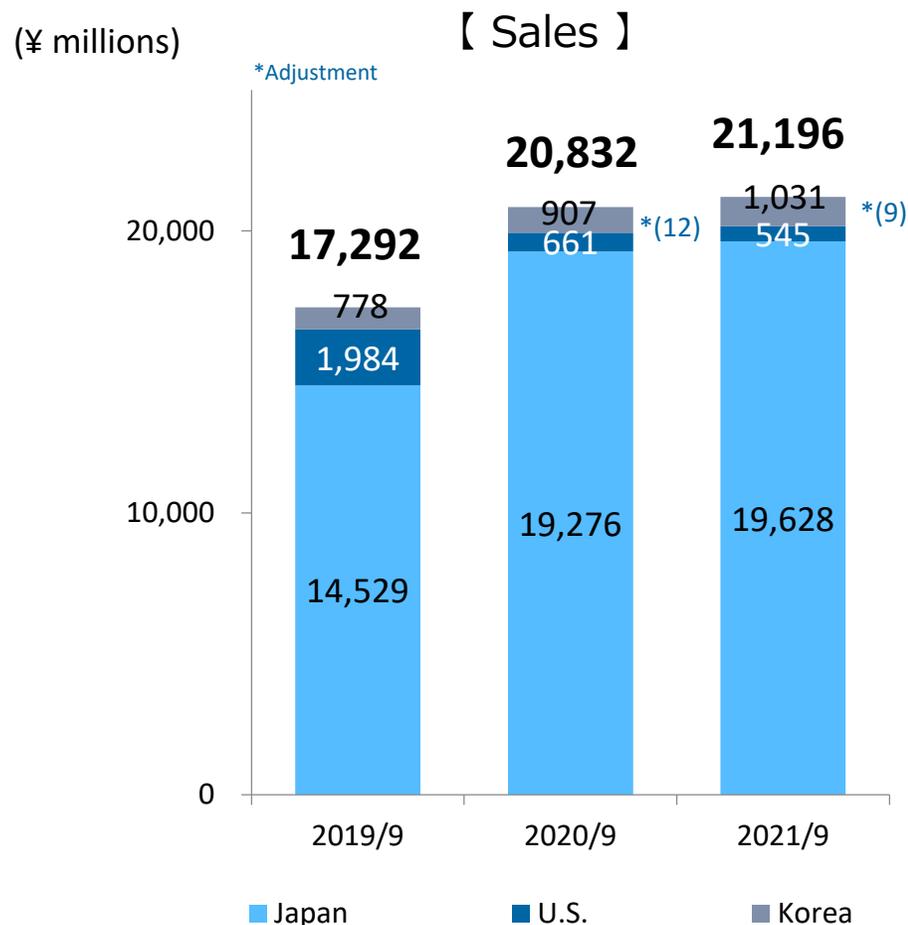
Contract Research Organization (CRO) Business



- 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 previous consolidated fiscal year thanks to the growth of non-clinical business and acquisition of new post-marketing and clinical operations projects related to COVID-19. Operating income went below the previous fiscal year due to factors such as generation of retirement benefit expenses.

Contract Development Manufacturing Organization (CDMO) Business



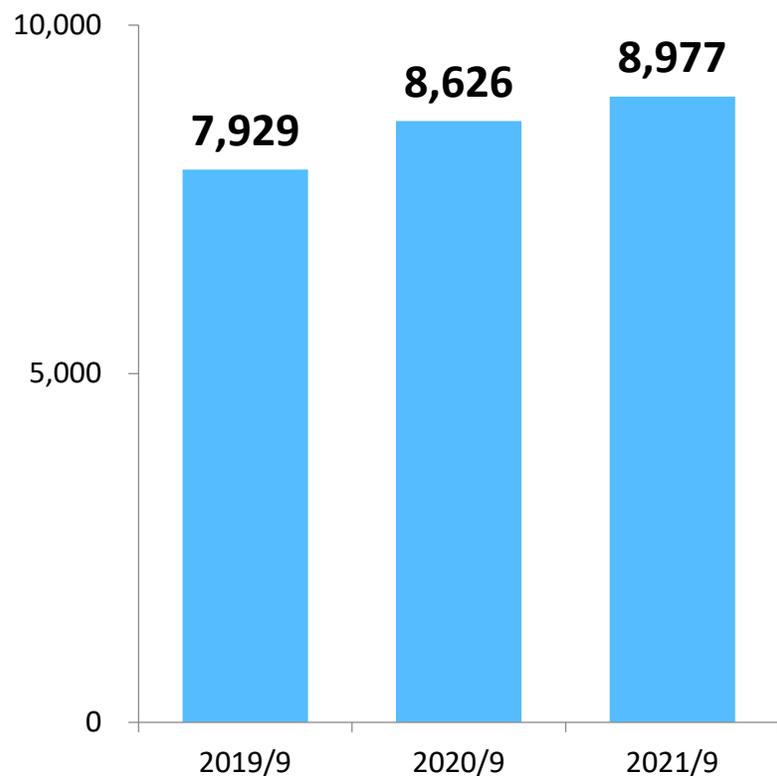
- Improve technical capabilities and quality, develop a low-cost production structure, and enhance competitiveness through strategic capital investment as a global pharmaceutical drug manufacturing platform that includes formulation design, investigational new drug manufacturing, and commercial production
- 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 previous consolidated fiscal year due to factors such as an increase in contracted production volume. As for operating income, while operating loss was recorded due to prior investment costs for the contract manufacturing business of biopharmaceutical APIs, due to the increase in sales, degree of deficit decreased compared to the previous consolidated fiscal year.

Contract Sales Organization (CSO) Business



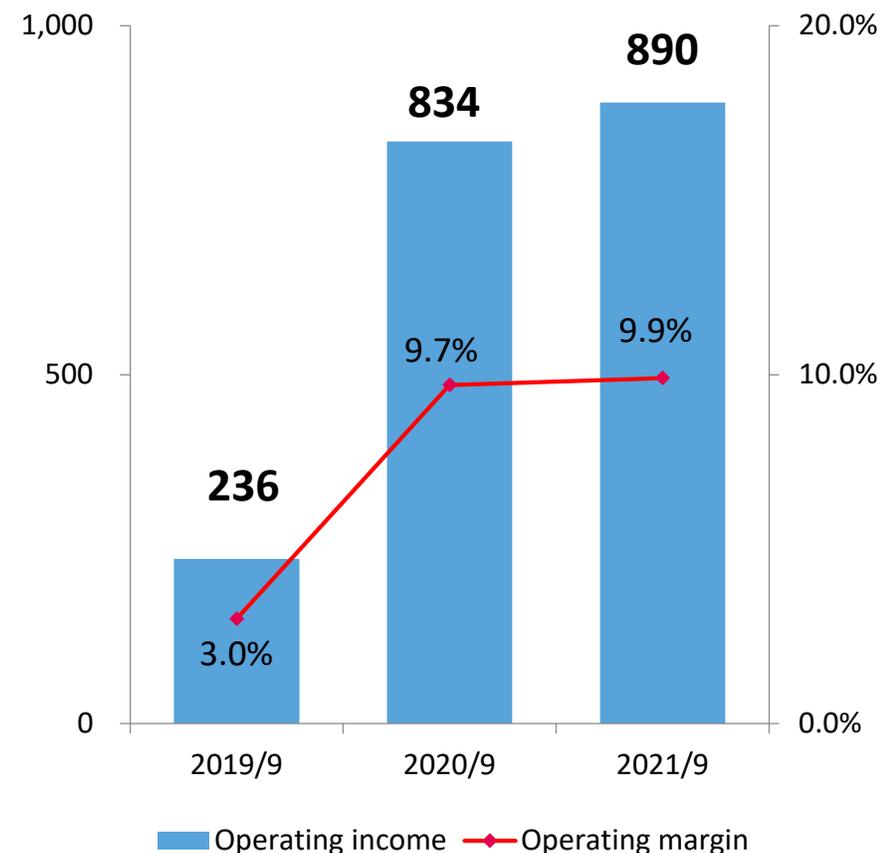
(¥ millions)

【 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.

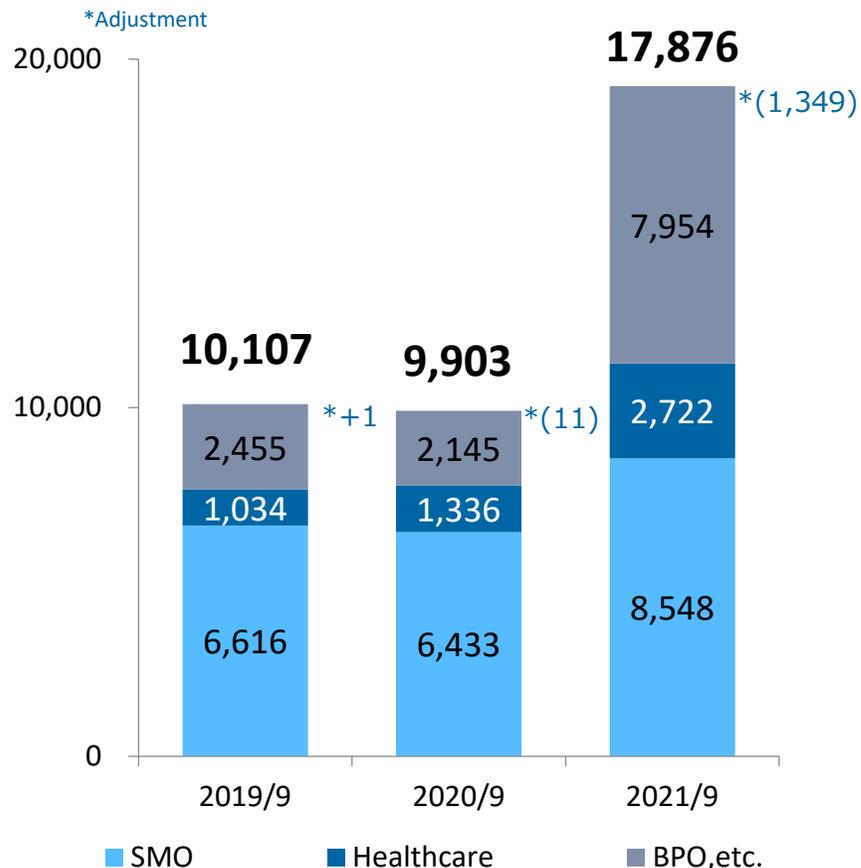
- Sales and operating income exceeded the previous consolidated fiscal year, thanks to the acquisition of new MR dispatch service projects.

Healthcare Business



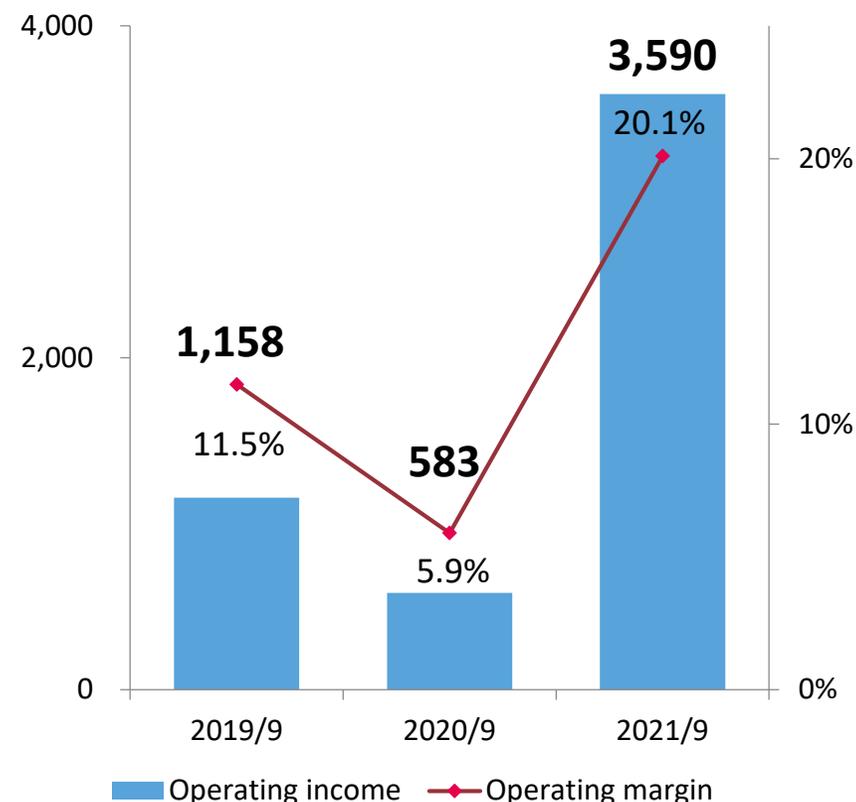
(¥ millions)

【 Sales 】



(¥ millions)

【 Operating income 】



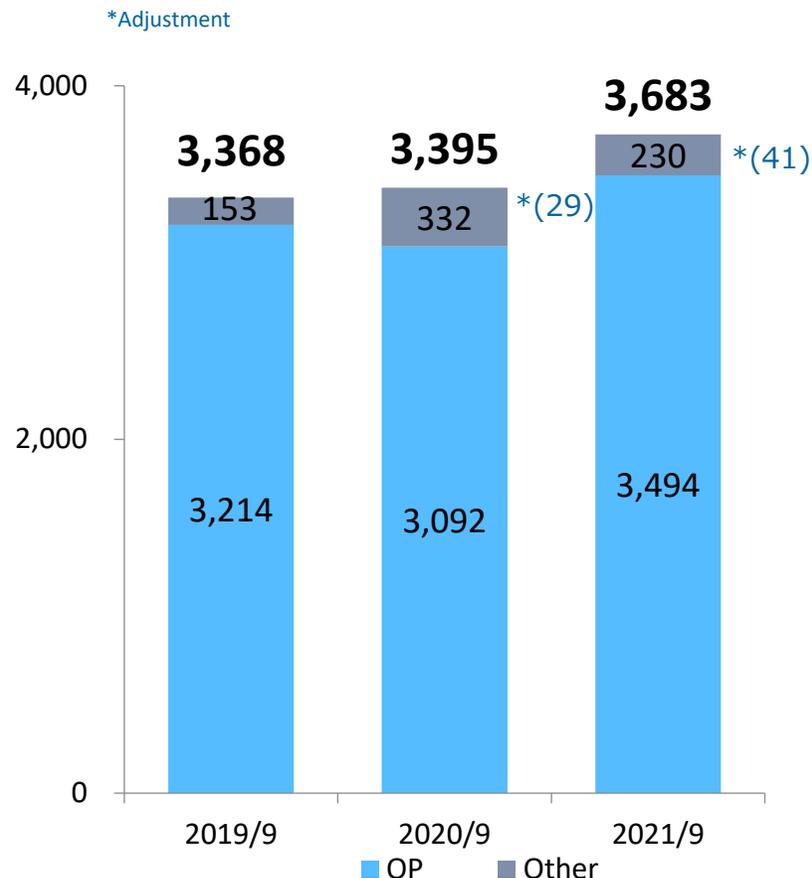
- Focus on supporting the development of effective treatment and preventive measures against COVID-19 infection, as well as supporting the PCR testing and vaccination by local governments.
- Work on the healthcare communication channel harmo® business and create business that contributes to the early detection of disease and prevention of disease aggravation.
- Sales were significantly above the previous consolidated fiscal year due to growth in the BPO and personnel services for vaccination support and SMO operations. Operating income was also significantly above the previous consolidated fiscal year due to an increase in sales, despite prior investments for the creation of new healthcare business.

Innovative Pharma Model (IPM) Business



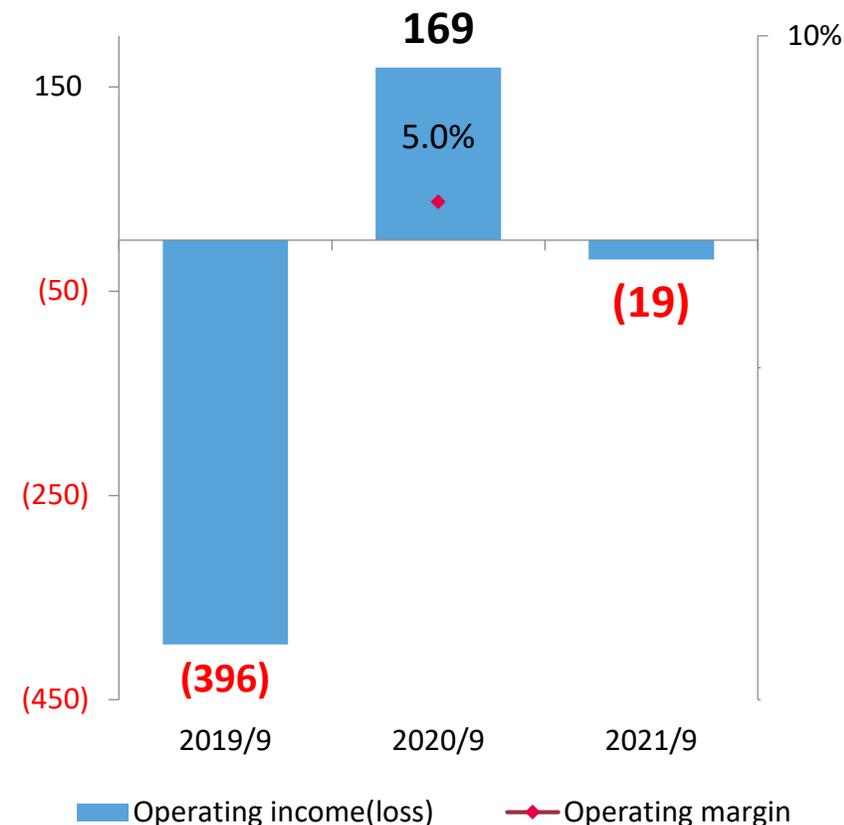
(¥ millions)

【 Sales 】



(¥ millions)

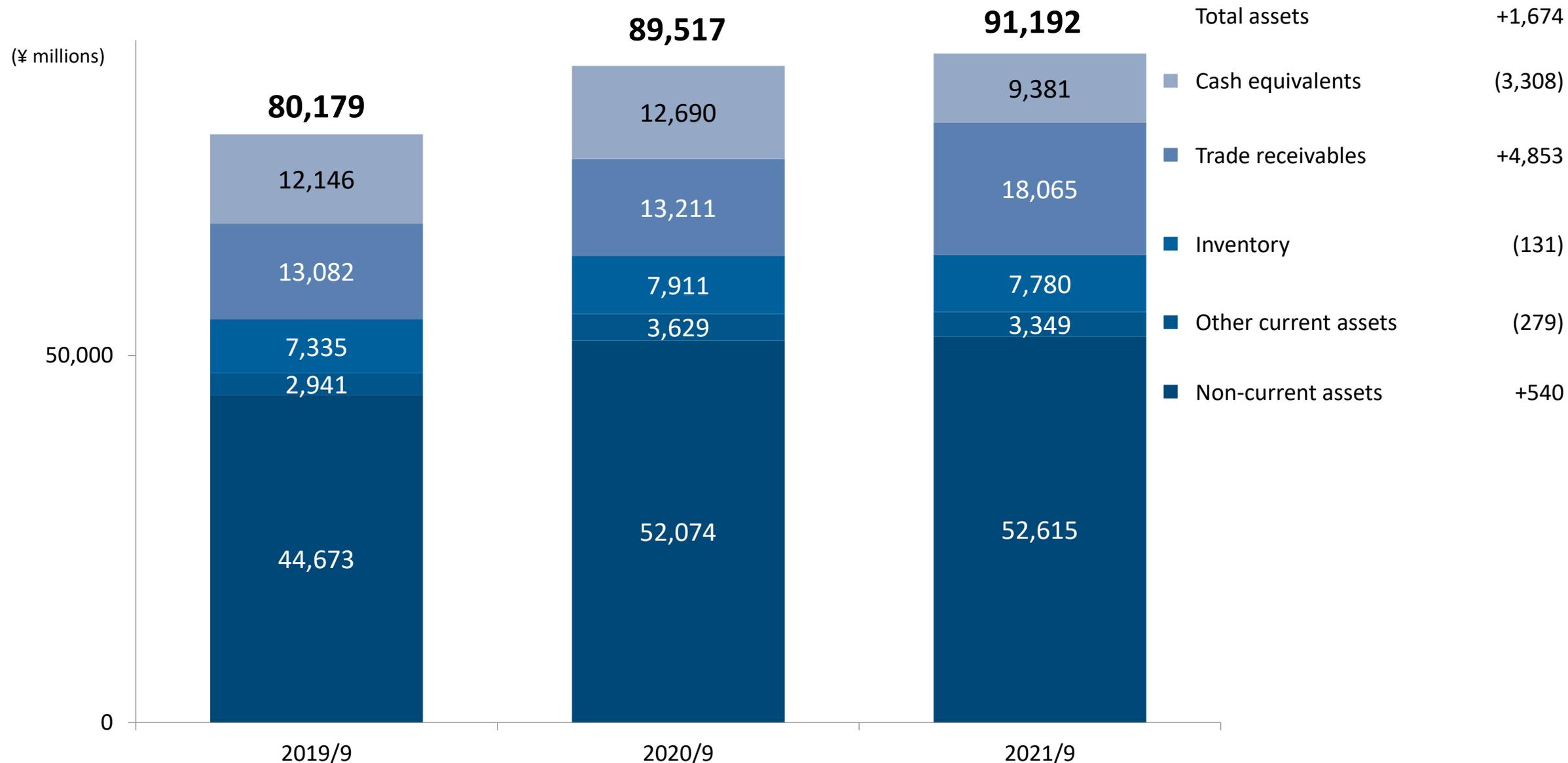
【 Operating income 】



- 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, we 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). In July 2021, we launched Lynspad™ for Intravenous Infusion 1000 mg of Grifols Therapeutics LLC in Japan for which we provided support toward the approval as an appointed marketing authorization holder. We will further expand our business scale and secure profitability by continuing to provide new business solutions.

- Sales exceeded the previous consolidated fiscal year thanks to new product launch. Operating income went below the previous fiscal year due to an increase of orphan drug R&D expenditure and registering an inventory valuation loss.

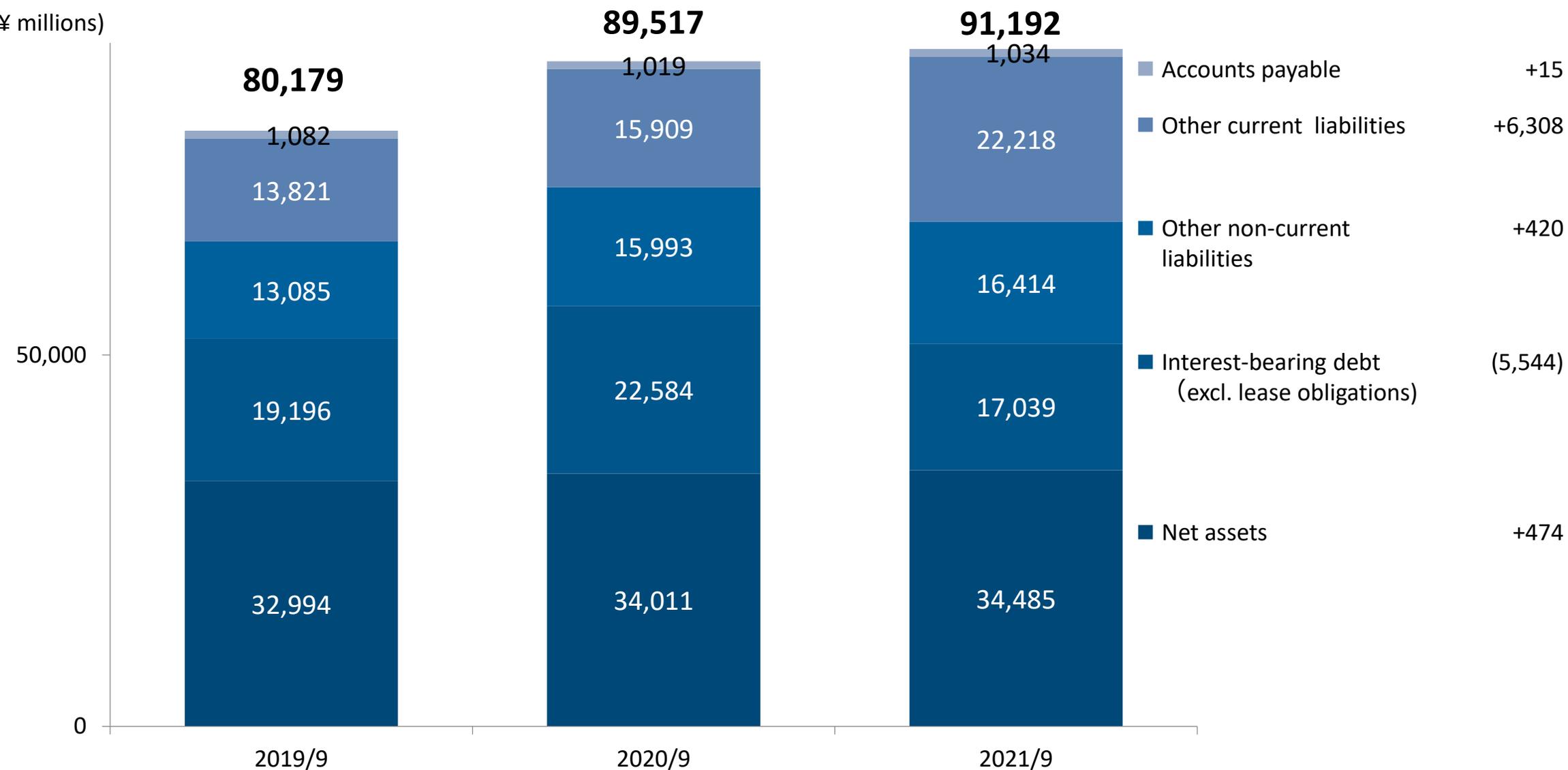
Consolidated balance sheet (assets)



Consolidated balance sheet (liabilities and net assets)



(¥ millions)



Cash Flows



(¥ millions)	2020/9	2021/9	Increase (decrease)	【Key factors】
Cash flows from operating activities	6,703	9,804	+3,100	(Cash flow from operating activities) • Increase in cash flow due to profit before income taxes and depreciation
Cash flows from investing activities	(8,542)	(6,685)	+1,857	(Cash flow from investing activities) • Expenditure from the acquisition of tangible fixed assets in the CDMO business
Cash flows from financing activities	2,354	(6,348)	(8,702)	(Cash flow from financing activities) • Expenditure from repayment of loans from financial institutions and payment for dividends
Effect of exchange rate change on cash and cash equivalents	42	(82)	(124)	
Net increase(decrease) in cash and cash equivalents	557	(3,310)	(3,868)	
Increase in cash and cash equivalents resulting from inclusion of subsidiaries in consolidation	—	1	+1	
Decrease in cash and cash equivalents resulting from exclusion of subsidiaries from consolidation	(14)	—	+14	
Cash and cash equivalents at beginning of period	12,144	12,688	+543	
Cash and cash equivalents at end of period	12,688	9,379	(3,308)	

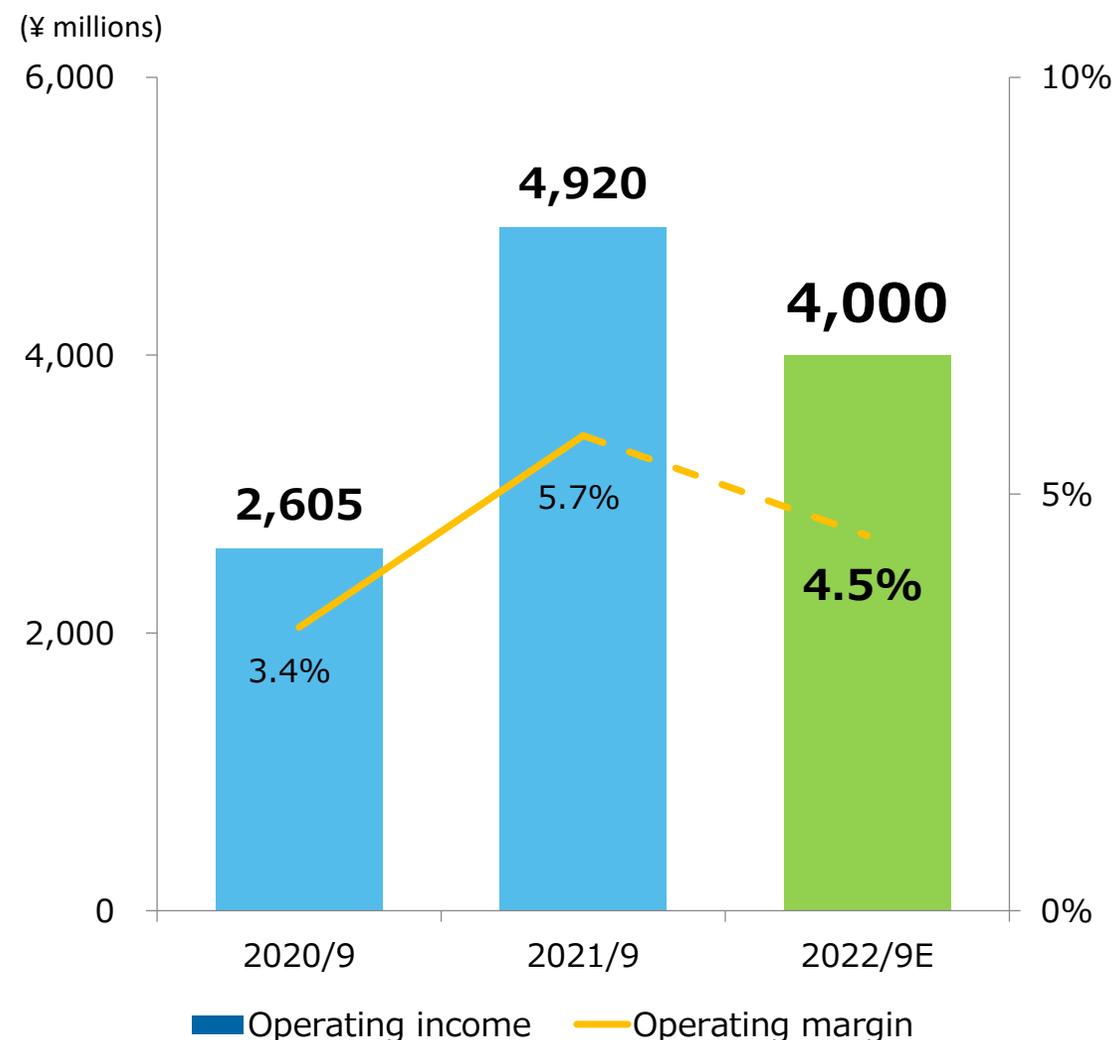


Forecast for FY ending Sep. 2022

Forecast for FY ending Sep. 2022



	2021/9 Actual (¥ millions)	2022/9 Forecast (¥ millions)	Change (%)
Net Sales	85,788	88,000	2.6
Operating income	4,920	4,000	(18.7)
Ordinary income	5,091	3,850	(24.4)
Profit attributable to owners of parent	1,879	2,050	1.3
Earnings per share	103.90	113.32	



* Because we are applying the new revenue recognition standard from September 2022, percentage change from previous term is for your reference only.



Cautionary statement:

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