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CHUGAI PHARMACEUTICAL CO., LTD.

A member of the Roche group

CONSOLIDATED FINANCIAL STATEMENTS (IFRS) (Non-Audited) (for the fiscal year 2021)

Name of Company: Chugai Pharmaceutical Co., Ltd. February 3, 2022
 Stock Listing: Tokyo Stock Exchange
 Security Code No.: 4519 (URL <https://www.chugai-pharm.co.jp/english>)
 Representative: Osamu Okuda, President & CEO
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 Phone: +81-(0)3-3273-0554
 Date of Annual General Meeting of Shareholders: March 29, 2022
 Date of Submission of Marketable Securities Filings: March 29, 2022
 Date on which Dividend Payments to Commence: March 30, 2022
 Supplementary Materials Prepared for the Financial Statements: Yes
 Presentation Held to Explain the Financial Statements: Yes (for institutional investors, securities analysts and the media)

(Note: Amounts of less than one million yen are rounded.)

1. Consolidated results for FY 2021 (January 1, 2021–December 31, 2021)

(1) Consolidated operating results

	Revenues	% change	Operating profit	% change	Net income	% change
FY ended Dec. 2021	¥999,759 million	27.0	¥421,897 million	40.1	¥302,995 million	41.1
FY ended Dec. 2020	¥786,946 million	14.7	¥301,230 million	43.0	¥214,733 million	36.3

	Net income attributable to Chugai shareholders	% change	Total comprehensive income	% change
FY ended Dec. 2021	¥302,995 million	41.1	¥306,020 million	41.2
FY ended Dec. 2020	¥214,733 million	36.3	¥216,748 million	39.7

	Earnings per share (Basic)	Earnings per share (Diluted)
FY ended Dec. 2021	¥184.29	¥184.17
FY ended Dec. 2020	¥130.66	¥130.53

	Ratio of net income to equity attributable to Chugai shareholders	Ratio of operating profit to revenues
FY ended Dec. 2021	28.0%	42.2%
FY ended Dec. 2020	23.4%	38.3%

Notes: 1. Percentages represent changes compared with the same period of the previous fiscal year.

2. Effective July 1, 2020, Chugai Pharmaceutical Co., Ltd. ("Chugai") implemented a three-for-one stock split of its common stock. "Earnings per share (Basic)" and "Earnings per share (Diluted)" are calculated based on the assumption that the stock split was implemented at the beginning of the previous fiscal year.

(2) Consolidated results (balance sheet)

	Total assets	Total equity	Equity attributable to Chugai shareholders	Ratio of equity attributable to Chugai shareholders	Equity per share attributable to Chugai shareholders
As of Dec. 31, 2021	¥1,538,694 million	¥1,188,017 million	¥1,188,017 million	77.2%	¥722.50
As of Dec. 31, 2020	¥1,235,498 million	¥980,003 million	¥980,003 million	79.3%	¥596.16

Note: Effective July 1, 2020, Chugai implemented a three-for-one stock split of its common stock. "Equity per share attributable to Chugai shareholders" is calculated based on the assumption that the stock split was implemented at the beginning of the previous fiscal year.

(3) Consolidated results (cash flow)

	Cash flows from operating activities	Cash flows from investing activities	Cash flows from financing activities	Balance of cash and cash equivalents
FY ended Dec. 31, 2021	¥279,626 million	¥(118,927) million	¥(107,408) million	¥267,753 million
FY ended Dec. 31, 2020	¥205,035 million	¥(98,312) million	¥(99,497) million	¥212,333 million

2. Dividends

	Annual dividends per share				
	End of first quarter	End of second quarter	End of third quarter	End of fiscal year	Total
FY ended Dec. 2020	—	¥75.00	—	¥30.00	—
FY ended Dec. 2021	—	¥30.00	—	¥46.00	¥76.00
FY ending Dec. 2022 (Forecast)	—	¥38.00	—	¥38.00	¥76.00

	Total dividends (annual)	Dividend payout ratio (consolidated)	Ratio of dividends to equity attributable to Chugai shareholders (consolidated)
FY ended Dec. 2020	¥90,411 million	42.1%	9.9%
FY ended Dec. 2021	¥124,965 million	41.2%	11.5%
FY ending Dec. 2022 (Forecast)		—%	

Note: Effective July 1, 2020, Chugai implemented a three-for-one stock split of its common stock. The dividend for the second quarter of the fiscal year 2020 presents the amount prior to the stock split. The annual dividend per share for the fiscal year ended December 31, 2020 is not stated because the amounts cannot be simply combined due to the implementation of the stock split. The annual dividend per share is ¥165 when calculated based on the assumption of no stock split, and ¥55 when calculated with the stock split taken into account.

3. Consolidated forecasts for FY 2022 (January 1, 2022–December 31, 2022)

	Revenues	% change	Core operating profit	% change	Core net income	% change
FY ending Dec. 2022 (Forecast)	¥1,150,000 million	+15.0	¥440,000 million	+1.4	¥312,500 million	+0.3
FY ended Dec. 2021 (Results)	¥999,759 million	+27.0	¥434,098 million	+41.0	¥311,516 million	+42.0

	Core earnings per share		Core dividend payout ratio %
FY ending Dec. 2022 (Forecast)	¥190.00	+0.3	40.0
FY ended Dec. 2021 (Results)	¥189.35	+42.0	40.1

Notes: 1. Percentages shown for revenues, Core operating profit, Core net income and Core EPS represent changes from the same period of the previous fiscal year.

2. The figures for the consolidated forecasts and actuals are calculated based on Core basis indicators established by Chugai and used on a consistent basis. Core EPS is diluted earnings per share attributable to Chugai shareholders on a Core basis.

4. Others

- (1) Changes in the state of material subsidiaries during the period (Changes in the state of specific subsidiaries with change in scope of consolidation): None
- (2) Changes in accounting policies and changes in accounting estimates
 - (a) Changes in accounting policies required by IFRS: None
 - (b) Changes in accounting policies other than those in (a) above: None
 - (c) Changes in accounting estimates: None

(3) Number of shares issued (common stock):

(a) Number of shares issued at the end of the period (including treasury stock)

As of Dec. 31, 2021	1,679,057,667	As of Dec. 31, 2020	1,679,057,667
As of Dec. 31, 2021	34,739,943	As of Dec. 31, 2020	35,186,586
FY ended Dec. 31, 2021	1,644,150,469	FY ended Dec. 31, 2020	1,643,445,409

(b) Number of treasury stock at the end of the period

(c) Average number of shares issued during the period

Notes: 1. For an explanation of the number of shares used for computing earnings per share (consolidated), please refer to "Earnings per share" on page 24 of the attached document.

2. Effective July 1, 2020, Chugai implemented a three-for-one stock split of its common stock. The number of shares issued (common stock) is calculated based on the assumption that the stock split was implemented at the beginning of the previous fiscal year.

Notes:

The consolidated financial statements are not subject to audits.

Explanation of the appropriate use of performance forecasts and other related items

(1) Portions of this report that refer to performance forecasts or any other future events are believed to be reasonable under information available at the time of the forecasts. Actual results may differ from these forecasts due to potential risks and uncertainties.

(2) The forecast which is published for shareholders and investors is based on the internal management indicator Core basis under International Financial Reporting Standards ("IFRS"). The difference between IFRS results and Core results will be explained at each event and presentation for the period.

(3) For the specifics of the forecasts, please refer to "Future outlook" on page 9, "Basic profit distribution principles and dividends for the fiscal year under review and the following fiscal year" on page 10, and "Management Principles and Goals" on page 11 - 16 of the attached document.

(4) Chugai is scheduled to hold a conference to explain the financial results as noted below. The presentation materials, the verbal recording, the Q&A, and other related documents will be posted on the Chugai's website following the conclusion of the conference.

Conference for institutional investors, securities analysts and the media (Japanese only): February 3, 2022, Thursday (Japan time).

The English translation of the presentation materials will be posted on the website on the next business day.

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1. Overview of Operating Results, etc.

(1) Overview of operating results for the fiscal year under review in billions of yen

	Year ended December 31		% change
	2021	2020	
Core results			
Revenues	999.8	786.9	+27.1
Sales	802.8	633.3	+26.8
Royalties and other operating income	196.9	153.6	+28.2
Cost of sales	(335.5)	(272.3)	+23.2
Gross profit	664.3	514.7	+29.1
Marketing and distribution	(75.8)	(71.5)	+6.0
Research and development	(129.8)	(113.5)	+14.4
General and administration	(24.6)	(21.7)	+13.4
Operating profit	434.1	307.9	+41.0
Net income	311.5	219.4	+42.0
IFRS results			
Revenues	999.8	786.9	+27.1
Operating profit	421.9	301.2	+40.1
Net income	303.0	214.7	+41.1

Consolidated financial highlights (IFRS results)

Revenues for the fiscal year under review were ¥999.8 billion (an increase of 27.1% year on year), operating profit for the fiscal year under review was ¥421.9 billion (an increase of 40.1% year on year), and net income for the fiscal year under review was ¥303.0 billion (an increase of 41.1% year on year). These results include non-Core items, such as amortization of intangible assets of ¥2.2 billion, impairment loss of intangible assets of ¥4.5 billion, and restructuring expenses etc. of ¥5.5 billion, which are excluded from the Core results that Chugai adopts to manage recurring business activities.

Consolidated financial highlights (Core results)

Revenues for the fiscal year under review were ¥999.8 billion (an increase of 27.1% year on year), due to significant increases in sales and royalties and other operating income.

Of revenues, sales were ¥802.8 billion (an increase of 26.8% year on year). Domestic sales grew significantly over the previous fiscal year due to favorable sales of mainstay products Tecentriq, Hemlibra, Kadcyla and Actemra, the steady market penetration of new products such as Enspryng and Polivy, and the supply of Ronapreve to the government, while sales were affected by the NHI drug price revisions and market penetration of generic drugs. Overseas sales increased considerably compared to the previous fiscal year since the export of Hemlibra to Roche increased significantly while the export of Actemra decreased substantially. Royalties and other operating income amounted to ¥196.9 billion (an increase of 28.2% year on year), mainly due to an increase in royalties related to Hemlibra and its profit-sharing income, despite a decrease in other operating income consisted of one-time income. Furthermore, cost to sales ratio was 41.8%, a 1.2 percentage points improvement year on year due to changes in product mix, etc. As a result, gross profit amounted to ¥664.3 billion (an increase of 29.1% year on year).

Operating expenses were ¥230.2 billion (an increase of 11.4% year on year). Marketing and distribution expenses were ¥75.8 billion (an increase of 6.0% year on year) due to the promotion of digital marketing, etc. Research and development expenses amounted to ¥129.8 billion (an increase of 14.4% year on year) due to an increase in expenses associated with the progress of projects, etc. General and administration expenses amounted to ¥24.6 billion (an increase of 13.4% year on year) primarily due to increases in the enterprise tax (pro forma standard taxation) and various expenses. As a result, Core operating profit was ¥434.1 billion (an increase of 41.0% year on year) and Core net income was ¥311.5 billion (an increase of 42.0% year on year).

Meanwhile, compared to the revised forecast announced on October 22, 2021, revenues increased by 3.1% to ¥999.8 billion, primarily due to an increase in export of Hemlibra to Roche, increases in royalties related to Actemra and Hemlibra and their profit-sharing income, and favorable domestic sales. The cost to sales ratio was 41.8%, an improvement of 1.6 percentage points over the revised forecast, reflecting a change in the product mix, etc. Operating expenses were ¥230.2 billion (a decrease of 0.3% compared to the revised forecast). As a result, Core operating profit was ¥434.1 billion (an increase of 8.5% compared to the revised forecast).

Note: Core results

Chugai discloses its results on a Core basis from 2013 in conjunction with its transition to IFRS. Core results are the results after adjusting non-recurring items recognized by Chugai to IFRS results, and are consistent with the Core concept disclosed by Roche. Core results are used by Chugai as an internal performance indicator, for explaining the status of recurring profits both internally and externally, and as the basis for payment-by-results.

For further details regarding the adjustment to IFRS results, please refer to the Supplementary Materials on page 1, entitled “Reconciliation of IFRS results to Core results.”

Sales breakdown in billions of yen

	Year ended December 31		
	2021	2020	% change
Sales	802.8	633.3	+26.8
Domestic sales	518.9	409.1	+26.8
Oncology	261.5	232.3	+12.6
Primary	257.4	176.8	+45.6
Overseas sales	283.9	224.2	+26.6

Domestic sales

Domestic sales were ¥518.9 billion (an increase of 26.8% year on year) mainly due to the favorable market penetration of mainstay products and new products, while sales were affected by the NHI drug price revisions of April 2020 and 2021 and the market penetration of generic drugs.

Oncology products sales were ¥261.5 billion (an increase of 12.6% year on year). Sales increased due to favorable sales of mainstay products with additional indication such as Tecentriq (an anti PD-L1 monoclonal antibody, anti-cancer agent) and Kadcyla (an anti-HER2 antibody-tubulin polymerization inhibitor conjugate), despite a sales decline of Herceptin (an anti-HER2 humanized monoclonal antibody, anti-cancer agent) and Rituxan (an anti-CD20 monoclonal antibody, anti-cancer agent) affected by the market penetration of generic drugs. The increase in sales was also attributable to Polivy (an anti-CD79b antibody-drug conjugate, anti-cancer agent), which was launched in May 2021, and growth in the number of tests provided by the Foundation Medicine genomic mutation analysis program*, for which new blood-based testing services were started in August 2021.

Primary products sales were ¥257.4 billion (an increase of 45.6% year on year). This was mainly due to the favorable sales of the mainstay products, Hemlibra (blood coagulation factor VIII substitute) and Actemra (a humanized anti-human IL-6 receptor monoclonal antibody), despite a sales decline of products such as Edirof (an osteoporosis agent) and Mircera (a long-acting erythropoiesis stimulating agent), affected by the market penetration of generic drugs and NHI drug price revisions. As for new products, posting sales from the supply of Ronapreve (anti-SARS-CoV-2 monoclonal antibody) to the government, which received the special approval for emergency in July 2021, contributed to sales, as did Enspryng (a pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody) and Evrysdi (SMN2 splicing modifier), which was launched in August 2021.

Meanwhile, compared to the revised forecast announced on October 22, 2021, domestic sales increased by 1.2% to ¥518.9 billion.

* “FoundationOne Liquid CDx Cancer Genomic Profiling” and “FoundationOne CDx Cancer Genomic Profiling”

Overseas sales

Overseas sales amounted to ¥283.9 billion (an increase of 26.6% year on year), far exceeding those of the previous fiscal year partly due to the depreciation of the yen over the previous fiscal year. In connection with full-scale exports to Roche at regular shipment prices, the export of Hemlibra increased significantly compared to the previous fiscal year, and the export of Alecensa also remained strong. On the other hand, the export of Actemra decreased significantly compared to the previous fiscal year, which was due to an increase in export of Actemra, including those for clinical trials for COVID-19 pneumonia, in the same period of the previous fiscal year.

Meanwhile, compared to the revised forecast announced on October 22, 2021, overseas sales increased by 5.7% to ¥283.9 billion.

R&D activities

In Japan and overseas, the Chugai Group (“the Group”) is actively engaged in prescription pharmaceutical R&D activities and is working to develop innovative products with global application. In Japan, the Group has established research bases in Fuji Gotemba and Kamakura, which are collaborating to develop new pharmaceuticals, and its research facilities in Ukima are conducting industrialization research. Overseas, Chugai Pharma USA, Inc. (United States); Chugai Pharma Europe Ltd. (United Kingdom); Chugai Pharma Science (Beijing) Co., Ltd. (China); and Chugai Pharma Taiwan Ltd. (Taiwan) are engaged in clinical development and submission of applications in their respective countries. Chugai Pharmabody Research Pte. Ltd. (Singapore) is engaged in pharmaceutical research and development.

In the fiscal year under review, R&D expenses on a Core basis totaled ¥129.8 billion (an increase of 14.4% year on year), and the ratio of R&D expenses to revenue was 13.0%.

Progress made in R&D activities during the period from January 1, 2021 to December 31, 2021 was as follows.

Oncology

- We obtained approval for the anti-CD79b antibody-drug conjugate RG7596 (Product name: Polivy) for the indication of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) in March and launched in May 2021. And we also filed for the treatment of previously untreated DLBCL in December 2021.
- We started global Phase III study for the engineered anti-PD-L1 monoclonal antibody RG7446 (Product name: Tecentriq) for the treatment of hepatocellular carcinoma (HCC) (intermediate stage), in combination with RG435, and muscle-invasive bladder cancer (adjuvant) in March and May 2021, respectively. And we also filed for the treatment of non-small cell lung cancer (NSCLC) (adjuvant) in July 2021.
- We started global Phase III study for the anti-VEGF (Vascular Endothelial Growth Factor) humanized monoclonal antibody RG435 (Product name: Avastin) for the treatment of HCC (intermediate stage), in combination with RG7446, in March 2021.
- We started global Phase III study for the selective estrogen receptor degrader (SERD) RG6171 for the treatment of breast cancer (adjuvant) in August 2021.
- We started global Phase III study for the anti-CD20/CD3 bispecific antibody RG7828 for the treatment of follicular lymphoma in October 2021.
- We started Phase I study for the RET inhibitor RG6396 for the treatment of solid tumors in July 2021. And we also started global Phase III study for the treatment of NSCLC in November 2021.
- We started Phase I study for the oncolytic type 5 adenovirus OBP-301 for the treatment of HCC, in combination with RG7446 and RG435, in January 2021.
- We started Phase I study for the anti-latent TGF-β1 monoclonal antibody SOF10/RG6440 for the treatment of solid tumors in June 2021
- We started Phase I study for the RAS inhibitor LUNA18 for the treatment of solid tumors in October 2021.
- We decided to discontinue the development of the anti-FAP humanized antibody-engineered IL-2 variant fusion protein RG7461 for solid tumors in consideration of the results of multiple overseas studies conducted by Roche.
- We decided to discontinue the development of the AKT inhibitor RG7440 for breast cancer in consideration of the results of the global study IPATunity150.

Renal disease

- We entered into an option and license agreement that Chugai will grant Alebund Pharmaceuticals (Hong Kong) Limited an exclusive license to develop, manufacture, and commercialize the NaPi-IIb, PiT-1, PiT-2 inhibitor EOS789 for all indications worldwide including Japan.

Autoimmune Diseases

- We decided to discontinue the development of the BTK inhibitor RG7845 for rheumatoid arthritis in consideration of the results of multiple overseas studies conducted by Roche.

Neurology

- We obtained approval for the SMN2 splicing modifier RG7916 (Product name: Evrysdi) for the treatment of spinal muscular atrophy in June 2021 and launched in August 2021.
- We obtained approval for the pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody SA237/RG6168 (Product name: Enspryng) for the indication of neuromyelitis optica spectrum disorder in the EU in June 2021. And we also started global Phase III study for the treatment of generalized myasthenia gravis (gMG) in October 2021.
- We started Phase I study for the anti-amyloid beta/TfR1 fusion protein RG6102 for the treatment of Alzheimer’s disease in July 2021.

Other Diseases

- We started Phase I study for the SARS-CoV-2 neutralizing antibody cocktail RG6413/RG6412 (Product name: Ronapreve) for the treatment of COVID-19 in March and filed for the special approval for emergency in June, and obtained approval for the treatment of COVID-19 in July 2021. And we also filed and obtained approval for additional indication as a preventive treatment of symptomatic COVID-19 in October and November 2021, respectively.
- We filed for the anti-coagulation factor IXa/X humanized bispecific monoclonal antibody ACE910/RG6013 (Product name: Hemlibra) for the treatment of acquired hemophilia A in November 2021.
- We filed for the humanized anti-human IL-6 receptor monoclonal antibody MRA/RG1569 (Product name: Actemra) for the treatment of COVID-19 pneumonia in December 2021.
- We filed for the anti-VEGF/Ang2 bispecific antibody RG7716 for the treatment of diabetic macular edema and neovascular age-related macular degeneration in June 2021. Also, we started global Phase III study for RG7716 for the treatment of retinal vein occlusion in March 2021.
- We started global Phase III study for the anti-C5 recycling antibody SKY59/RG6107 for the treatment of atypical hemolytic uremic syndrome in October 2021.
- We started Phase I study for the anti-FGFR1/KLB bispecific antibody RG7992 for the treatment of non-alcoholic steatohepatitis in June 2021.
- We started global Phase III study for the RNA polymerase inhibitor RG6422 for the treatment of COVID-19 in April 2021. We decided to discontinue the development considering the decision made by Roche and Atea to terminate their partnership for the global joint development of RG6422.
- We decided to discontinue the development of the PTH1 receptor agonist PCO371 for hypoparathyroidism in consideration of the results of Phase I study.
- We decided to discontinue the development of the sodium hyaluronate NRD101 (Product name: Suvenyl) for knee osteoarthritis/shoulder periarthritis in China in consideration of business strategy.

Note: In (1), amounts less than ¥0.1 billion have been rounded to the nearest ¥0.1 billion. Figures for changes in amounts and percentages have been calculated using data denominated in ¥0.1 billion units.

(2) Overview of financial position for the fiscal year under review in billions of yen

	December 31, 2021	December 31, 2020	Change in amount
Net operating assets (NOA) and Net assets			
Net working capital	370.1	300.0	70.1
Long-term net operating assets	402.4	346.0	56.4
Net operating assets (NOA)	772.6	646.0	126.6
Net cash	472.0	378.6	93.4
Other non-operating assets – net	(56.5)	(44.6)	(11.9)
Total net assets	1,188.0	980.0	208.0
Consolidated balance sheet (IFRS basis)			
Total assets	1,538.7	1,235.5	303.2
Total liabilities	(350.7)	(255.5)	(95.2)
Total net assets	1,188.0	980.0	208.0

Net operating assets (NOA) at December 31, 2021 were ¥772.6 billion, an increase of ¥126.6 billion since the end of the previous fiscal year. Of NOA, net working capital was ¥370.1 billion (an increase of ¥70.1 billion since the end of the previous fiscal year), due mainly to an increase in accounts receivable. Long-term net operating assets increased by ¥56.4 billion to ¥402.4 billion since the end of the previous fiscal year, mainly due to the investments in the Chugai Life Science Park Yokohama and the manufacturing building for active pharmaceutical ingredients (APIs) (FJ3) in the Fujieda Plant.

As indicated in “(3) Overview of cash flows for the fiscal year under review” on the next page, net cash, including marketable securities and interest-bearing debt, increased by ¥93.4 billion since the end of the previous fiscal year to ¥472.0 billion. Other non-operating assets – net decreased by ¥11.9 billion since the end of the previous fiscal year to ¥(56.5) billion, due mainly to an increase in current income tax liabilities.

As a consequence, total net assets were ¥1,188.0 billion (an increase of ¥208.0 billion since the end of the previous fiscal year).

Note: Net operating assets (NOA) and Net assets

The consolidated balance sheet has been prepared in accordance with International Accounting Standards (IAS) No. 1, “Presentation of Financial Statements.” On the other hand, Net operating assets (NOA) and Net assets are a reconfiguration of the consolidated balance sheet as internal indicators and are identical to the indicators disclosed by Roche. Furthermore, no items from Net operating assets (NOA) and Net assets have been excluded, as the Core results concept only applies to the income statement.

For further details, please refer to the Supplementary Materials on page 8, entitled “Financial position.”

Note: Net operating assets (NOA)

Net operating assets allow for an assessment of the Group’s operating performance of the business independently from financing and tax activities. Net operating assets are calculated as net working capital, long-term net operating assets that includes property, plant and equipment, intangible assets etc. minus provisions.

Note: In (2), amounts less than ¥0.1 billion have been rounded to the nearest ¥0.1 billion. Figures for changes in amounts have been calculated using data denominated in ¥0.1 billion units.

(3) Overview of cash flows for the fiscal year under review in billions of yen

	Year ended December 31		% change
	2021	2020	
Free cash flows			
Operating profit - IFRS basis	421.9	301.2	+40.1
Operating profit, net of operating cash adjustments	466.4	335.5	+39.0
Operating free cash flows	301.4	201.2	+49.8
Free cash flows	189.4	135.4	+39.9
Net change in net cash	93.4	45.5	+105.3
Consolidated statement of cash flows (IFRS basis)			
Cash flows from operating activities	279.6	205.0	+36.4
Cash flows from investing activities	(118.9)	(98.3)	+21.0
Cash flows from financing activities	(107.4)	(99.5)	+7.9
Net change in cash and cash equivalents	55.5	8.4	+560.7
Cash and cash equivalents at December 31	267.8	212.3	+26.1

Operating profit, net of operating cash adjustments, amounted to ¥466.4 billion (an increase of 39.0% year on year), which was calculated by adjusting for depreciation and other items that are included in operating profit but are not accompanied by cash inflows or outflows and all inflows and outflows related to NOA that are not accompanied by profit and loss.

Operating free cash flows for the fiscal year under review amounted to a net inflow of ¥301.4 billion (an increase of 49.8% year on year) due to an increase in operating profit, etc., despite an increase in net working capital, etc. of ¥83.1 billion, as well as expenditures of ¥66.0 billion for the purchase of property, plant and equipment. Factors accounting for the increase in net working capital, etc. are as indicated in “(2) Overview of financial position for the fiscal year under review.”

Free cash flows were a net cash inflow of ¥189.4 billion (an increase of 39.9% year on year) due mainly to income taxes paid of ¥104.1 billion.

The net change in net cash calculated by subtracting dividends paid of ¥98.6 billion, etc. from free cash flows was an increase of ¥93.4 billion.

The net change in cash and cash equivalents, excluding changes in marketable securities and interest-bearing debt, was a net cash inflow of ¥55.5 billion. The cash and cash equivalents balance at the end of this period amounted to ¥267.8 billion.

Note: Free cash flows (FCF)

The consolidated statement of cash flows has been prepared in accordance with International Accounting Standard (IAS) No. 7, “Statement of Cash Flows.” FCF is a reconfiguration of the consolidated statement of cash flows as internal indicators and is identical to the indicators disclosed by Roche. Furthermore, no items from FCF have been excluded, as the Core results concept only applies to the income statement.

For further details, please refer to the Supplementary Materials on page 9, entitled “Cash flows.”

Cash flow related indicators

	Year ended December 31			
	2021	2020	2019	2018
Ratio of equity attributable to Chugai shareholders (%)	77.2	79.3	80.6	82.2
Ratio of equity attributable to Chugai shareholders on a market basis (%)	399.1	732.2	521.2	379.7
Interest-bearing debt to cash flows ratio (%)	—	—	—	0.2
Interest-coverage ratio (times)	5,861.7	6,067.7	7,537.5	26,274.1

Ratio of equity attributable to Chugai shareholders: $\text{Equity attributable to Chugai shareholders} / \text{Total assets}$
Ratio of equity attributable to Chugai shareholders on a market basis: $\text{Total market capitalization} / \text{Total assets}$
Interest-bearing debt to cash flows ratio: $\text{Interest-bearing debt} / \text{Cash flows}$
Interest-coverage ratio: $\text{Cash flows} / \text{Interest payments}$

Notes:

- All of the figures in the aforementioned indicators were calculated on a consolidated basis.*
- Total market capitalization was calculated by multiplying the closing stock price at the end of the period by the total number of outstanding shares at the end of the period (excluding treasury stock).*
- Cash flows from operating activities in the consolidated statement of cash flows were used as cash flows in the calculations above.*
- Interest-bearing debt refers to all debt posted in the consolidated balance sheet upon which interest is paid.*
- Interest paid in the consolidated statement of cash flows was used as interest payment in the calculations above.*

Note: In (3), amounts less than ¥0.1 billion have been rounded to the nearest ¥0.1 billion. Figures for changes in amounts and percentages have been calculated using data denominated in ¥0.1 billion units.

(4) Future outlook**Forecast assumptions**

In preparing Chugai performance outlook, Chugai has assumed exchange rates of ¥122/CHF, ¥130/EUR, ¥112/USD, and ¥84/SGD.

Outlook for the fiscal year**Revenues**

Domestic sales are expected to increase to ¥646.3 billion (an increase of 24.6% year on year) due to the sales growth in new products such as Ronapreve, Polivy, Enspryng, Evrysdi, etc., and the mainstay products including Hemlibra despite the negative impact from intensifying competition associated primarily with launches of biosimilars and generics as well as NHI drug price revisions.

Overseas sales are expected to increase to the amount of ¥385.2 billion (an increase of 35.7% year on year), mainly due to a steady sales growth in Hemlibra, for which export to Roche at a regular shipment price was started in full scale in the previous fiscal year, amid an increase in sales of Actemra.

Royalties and other operating income are expected to reach ¥118.5 billion (a decrease of 39.8% year on year). Royalty and profit-sharing income are forecasted to decrease to ¥114.0 billion (a decrease of 39.1% year on year) because of a decrease in royalties from Roche mainly for the stock of initial shipment of Hemlibra. Other operating income is expected to decrease to ¥4.5 billion (a decrease of 54.1% year on year) due to a decrease of one-time income.

Core Operating Profit / Core EPS

Gross profit is expected to rise to ¥690.0 billion (an increase of 3.9% year on year), assuming a 2.8 percentage point increase year on year of the cost to sales ratio to 44.6%, due to a change in the product mix, etc., in addition to an increase in revenues. On the other hand, total expenses are expected to be the amount of ¥250.0 billion (an increase of 8.6% year on year). Particularly, expenses for research and development are expected to increase to ¥149.5 billion (an increase of 15.2% year on year) due to the increase of research and development activities such as progress in development themes.

Core operating profit is expected to be ¥440.0 billion (an increase of 1.4% year on year) and Core net income is expected to be ¥312.5 billion (an increase of 0.3% year on year). Core EPS is forecasted to be ¥190.00 (an increase of 0.3% year on year).

(Billions of yen)

	Outlook for FY 2022	% change
Revenues	1,150.0	+15.0
Sales	1,031.5	+28.5
Core operating profit	440.0	+1.4
Core net income	312.5	+0.3

Note: In (4), amounts less than ¥0.1 billion have been rounded to the nearest ¥0.1 billion. Figures for changes in amounts and percentages have been calculated using data denominated in ¥0.1 billion units.

(5) Basic profit distribution principles and dividends for the fiscal year under review and the following fiscal year

Taking into account strategic funding needs and earnings prospects, Chugai sets a target for consolidated dividend payout ratio of 45% on average in comparison with Core EPS, with an aim to continuously provide a stable allocation of profit to all shareholders. In addition, internal reserves will be used to increase corporate value through investments to attain further growth in existing strategic domains and to identify future business opportunities.

In the fiscal year ended December 31, 2021, Chugai achieved the highest results in the past, which resulted in Core EPS increasing by 42.0% year on year.

Reflecting the favorable results and based on our principles of “a stable allocation of profit” and “aiming for a consolidated dividend payout ratio of 45% on average in comparison with Core EPS,” year-end dividends for the fiscal year ended December 31, 2021 are planned to be ¥46 per share. As a result, the annual dividend per share will be ¥76 per share, and the Core dividend payout ratio is 40.1% (an average of 42.9% for the past five years).

For the following fiscal year ending December 31, 2022, Chugai expects annual dividends of ¥76 including interim dividends of ¥38. As a result, the Core dividend payout ratio for 2022 is expected to be 40.0% (41.9% on a five-year average basis).

	Amount decided	Latest forecast for dividend (October 22, 2021)	Actual in the previous fiscal year (ended Dec. 31, 2020)
Record date	December 31, 2021	December 31, 2021	December 31, 2020
Dividends per share	¥46.00	Undecided	¥30.00
Total dividends	¥75,639 million	—	¥49,316 million
Effective date	March 30, 2022	—	March 24, 2021
Dividend resource	Retained earnings	—	Retained earnings

2. Management Principles and Goals

(1) Basic management principles

In line with its strategic alliance with the world-leading pharmaceutical company Roche, the Group's basic management principles are to develop hand in hand with society under its mission of "dedicating ourselves to adding value by creating and delivering innovative products and services for the medical community and human health around the world" and its Envisioned Future of "becoming a top innovator for advanced and sustainable patient-centric healthcare."

As the Group works to achieve these goals, it will carry out its business activities in line with its core values of "Patient Centric," "Pioneering Spirit" and "Integrity."

Under these basic management principles, the Group focuses on innovation based on innovative drug discovery, with the aim of resolving social issues through the provision of optimal medical care for each and every patient, while also expanding corporate value in a sustainable manner.

To create shared value for Chugai and society, the Group identifies material issues that should be given priority. The Group will proactively work on social issues including those in ESG and SDGs, for example, "sustainable healthcare," which is also stated in its Envisioned Future. The Group is convinced that these activities will contribute to enhancing the sustainability of society as a whole, while laying a foundation for the long-term development of the Group.

(2) Target management indicators

The Group places emphasis on increasing corporate value by generating innovation, and prioritizes the allocation of management resources to the development of innovative new drugs. The Group works to conduct flexible and agile business operations, in order to achieve stable profit growth over the short- to medium-term, while focusing on Core ROIC as an indicator of investment efficiency over the long term. In addition, whenever making investment decisions such as individual development projects, the Group carries out an evaluation of investment value based on capital costs, and makes decisions with emphasis on profitability and efficiency.

Under such policy, due to a drastic change in Chugai's revenue structure, innovative products developed in-house have gained importance in terms of revenue, in recent years. As the sources of revenue have expanded to markets around the world, revenue is now affected more than ever by overseas market trends. As for the external environment, the competitive environment is changing significantly, as seen by the digitization of the healthcare industry, the evolution of drug discovery technologies, issues regarding sources of medical financing, and active business combinations and alliances.

Against the backdrop of such a rapidly changing business environment, the Group has formulated a growth strategy toward 2030, "TOP I 2030" (described later), where it has set the goals of "Double R&D output" and "Launch global in-house products every year." At the same time, the Group has determined to stop formulating medium-term (three years) plans. Instead, the Group sets and manages goals at the midpoint (in three to five years) as medium-term milestones so that it can fill the gap between the current state and goals by backcasting from the long-term goals. In this way, the Group aims to achieve its long-term goals while modifying plans in an agile and flexible manner in accordance with the progress of the plans and changes in the environment. The Group will continue to disclose the status of progress of its business activities, by explaining business strategies and the outlook for R&D pipelines, and indicate the path for achieving these objectives. The Group plans to continue disclosing annual earnings forecasts and providing explanation on the management status at briefing sessions and other meetings, in order to report the progress of the business strategies set forth by Chugai in a timely manner.

(3) Management environment and issues to be addressed

There are growing expectations and needs for pharmaceuticals due to an increase in the world population, progressive demographic graying in each country and the global COVID-19 pandemic continuing from 2020. At the same time, more and more stringent policies to curb medical expenditures, including drug costs, are being implemented amid the strain on budgets in each country due to an increase in social security costs such as medical expenditures. The realization of sustainable medical care has become a common issue in the world. As such, in order to realize advanced and sustainable medical care with limited resources, the trend toward VBHC (Value Based Healthcare) is gaining momentum, in which only solutions that offer true value are pursued.

As the dramatic progress of life science and digital technologies has resulted in expanded opportunities to generate innovation for solving medical issues, digital companies as well as various other players are now entering the healthcare area. As a result, competition beyond the scope of existing industries is intensifying more than ever.

Under these circumstances, "the pursuit of innovation" is the most important challenge in order to fulfill the Group's mission of providing innovative drugs. In order to realize optimal medical care for each and every patient, there is a need for the development of new drugs that respond to unmet medical needs through the search for new therapy targets and further innovation in drug discovery technologies. The key to securing a competitive advantage

is to acquire and enhance capabilities that break through conventional drug discovery abilities, while flexibly incorporating new technologies that leverage advances in life sciences as well as the evolution of digital technologies such as big data and AI. In addition, amid an increasingly severe business environment for pharmaceutical companies due to increased financial pressure on a worldwide scale, there is even greater need of transformation to a structure that enables concentrated investment of limited resources on innovation.

The Group achieved top-class growth in Japan based on the development of innovative new drugs and its strategic alliance with Roche. While securing a stable revenue foundation through Roche's fully stocked pipeline of new drugs as well as leveraging the Roche global platform for the Group's late-stage development and sales activities to achieve a high level of productivity, the Group concentrates resources on in-house drug discovery and continuously generates innovative R&D projects. As a result, the Group's drug discovery capabilities have been highly evaluated worldwide, with six drugs (including Actemra, Alecensa, Hemlibra, Enspryng and Nemolizumab) generated by Chugai being designated as Breakthrough Therapy* by the U.S. Food and Drug Administration (FDA).

Going forward, the Group will steadily maximize value for these growth drivers in the global market, while generating the next innovative new drugs ahead of competitors through swift development and demonstrating high patient value, in an aim for sustainable profit growth. In addition, amid a rising need for diagnosis, prevention and treatment of COVID-19, the Group will strive to maintain a stable supply of Actemra and Ronapreve and continue to work to develop and deliver innovative medicines.

In addition to the above-mentioned challenges to realize sustainable medical care, there is a global challenge of growing threats to the sustainability of the social system, including changes in the global environment and widening economic disparity. Chugai includes those social issues in its material issues so as to continue to strive for the resolution.

* Breakthrough Therapy: Drug candidates that are expected to be more effective than existing therapies for treating serious or life-threatening diseases or conditions.

(4) Growth strategy for 2030 “TOP I 2030”

With a view toward realizing the Envisioned Future set out in its Mission Statement, the Group has formulated and implemented “TOP I 2030,” a growth strategy to achieve this goal since 2021, while materializing the vision of what it means to be a top innovator by 2030.

Our envisioned Top Innovator in 2030:

1. “Expectation from patients all over the world”
A company with drug discovery capabilities that meet the world's highest standards, and which offers hope to patients around the world, that “Chugai will surely create new treatments”
2. “Attracting talent and players from around the world”
A company that attracts passionate talent from all over the world, and inspire players involved in healthcare around the world to think they can create something new by partnering with Chugai
3. “Role model for the world”
A company that serves as a global role model, due to recognition for its ESG initiatives through its business activities, and by playing a leading role in solving social issues

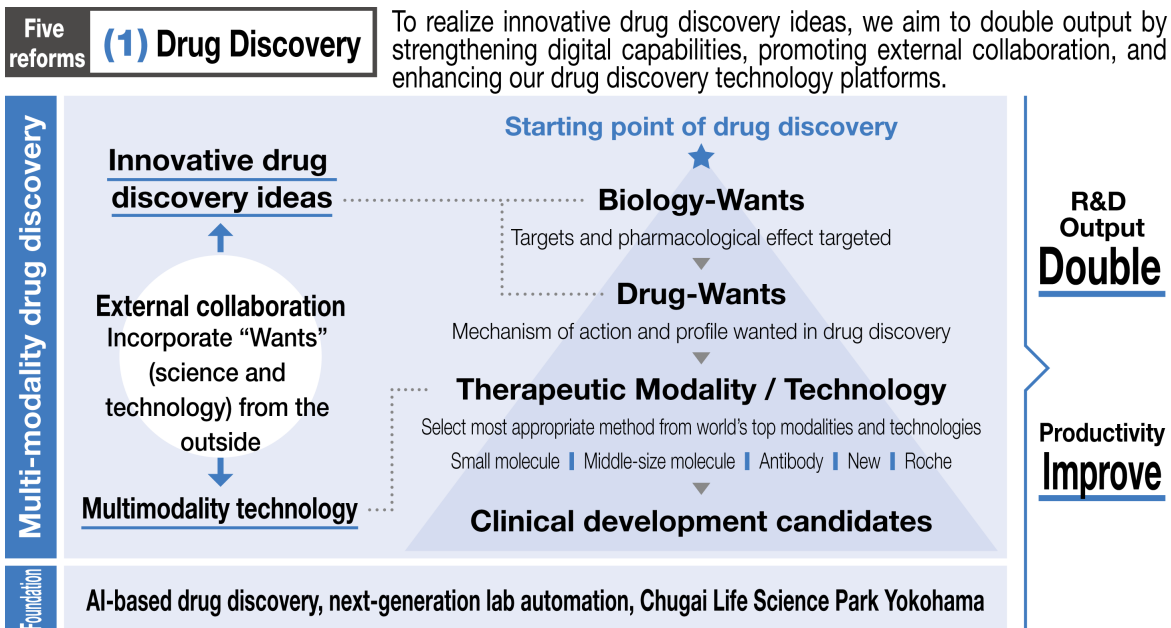
The twin pillars of “TOP I 2030” consist of “Global First-Class Drug Discovery” and “Futuristic Business Model.”

By making use of its unique science and technology, Chugai has successfully created numerous innovative new drugs. In the next decade, the Group will seek to build and strengthen its system for continuously delivering solutions that respond to the unmet medical needs of the world, while making substantial improvements to its drug discovery capabilities. Specifically, the Group aims to double its current R&D output over the next ten years, in order to become a company that is capable of launching innovative in-house developed global products every year.

The Group will also work on creating an advanced business model that takes into account changes in the environment and technological evolution. In particular, the Group aims to dramatically improve productivity throughout its value chain, and to expand value and product value for each and every patient, by fundamentally restructuring our processes and the value creation model through the utilization of digital technology in all value chains.

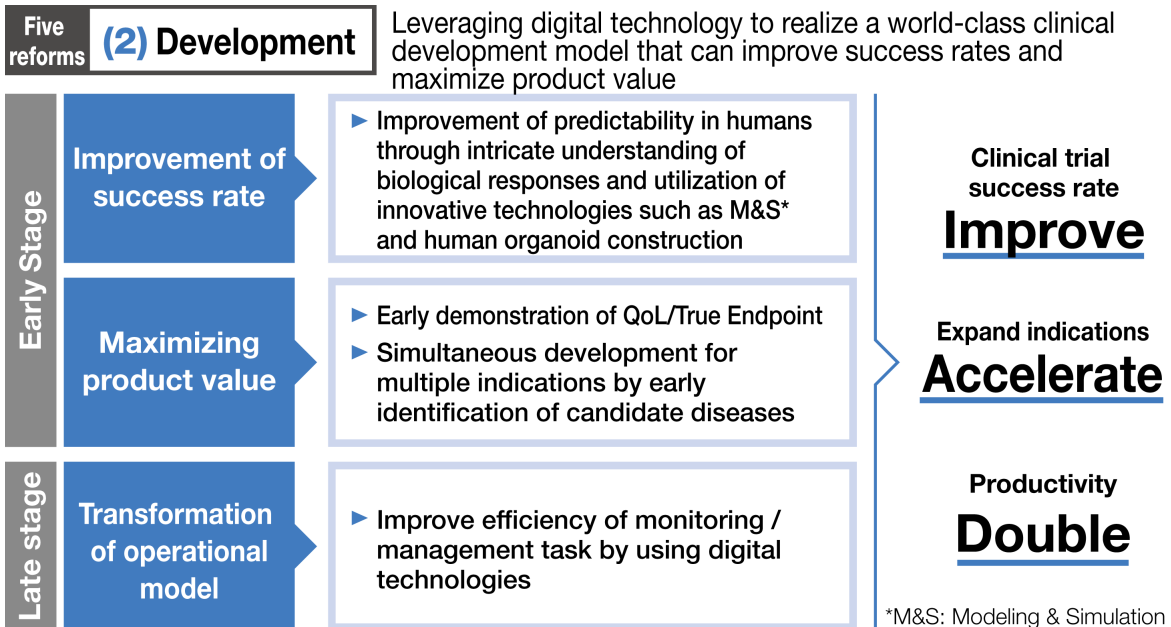
As specific initiatives, the Group has set forth “five reforms” in line with its value chain to realize the twin pillars of the strategy. These reforms comprise “Drug Discovery,” “Development,” “Pharmaceutical Technology,” “Value Delivery” and “Foundation for Growth.”

1) Drug Discovery



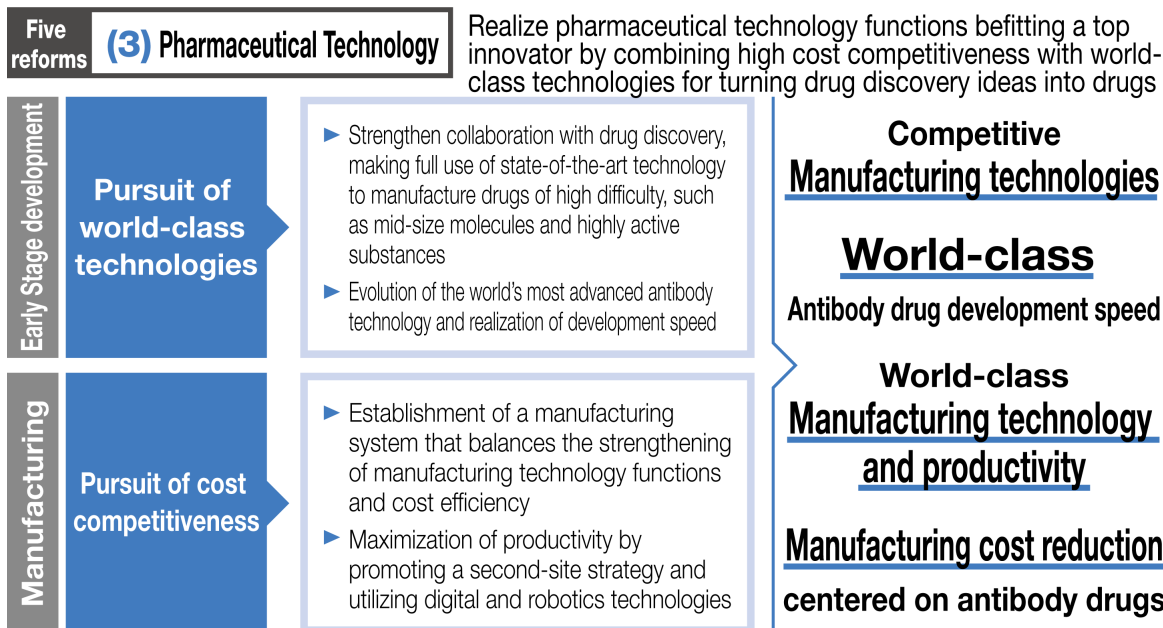
In “TOP I 2030,” the Group will aim to further strengthen its drug discovery technology foundation, in order to materialize original drug discovery ideas based on its accumulated strengths in drug discovery, including protein engineering technology. In addition, the Group will concentrate resources on a company-wide basis, on drug discovery and early development, in order to create maximum value and produce results with adequate investment. In particular, in mid-size molecule drugs, which are expected to drive the Group’s medium- to long-term growth, the Group will give priority to investing resources in technology development and clinical projects for early commercialization. The Group will also strive to diversify and accelerate drug discovery technologies, through the effective utilization of digital technologies including AI, as well as proactive external collaboration.

2) Development



In order to deliver ground-breaking projects, as quickly as possible to as many patients as possible, the Group will build a top-class clinical development model in the industry that makes maximum use of mathematical models and digital technologies. The Group will enhance the predictability of dosing options, efficacy, and safety by precisely understanding biological reactions and thoroughly utilizing various disease and treatment data accumulated in-house, as well as real-world data (RWD). At the same time, the Group will utilize digital biomarkers and digital devices to demonstrate the QoL of patients at an early stage. In addition, the Group will work on a fundamental reform of its operations model, such as enhancing operational efficiency of late-stage clinical development and reducing the size and duration of studies through the use of RWD and other data.

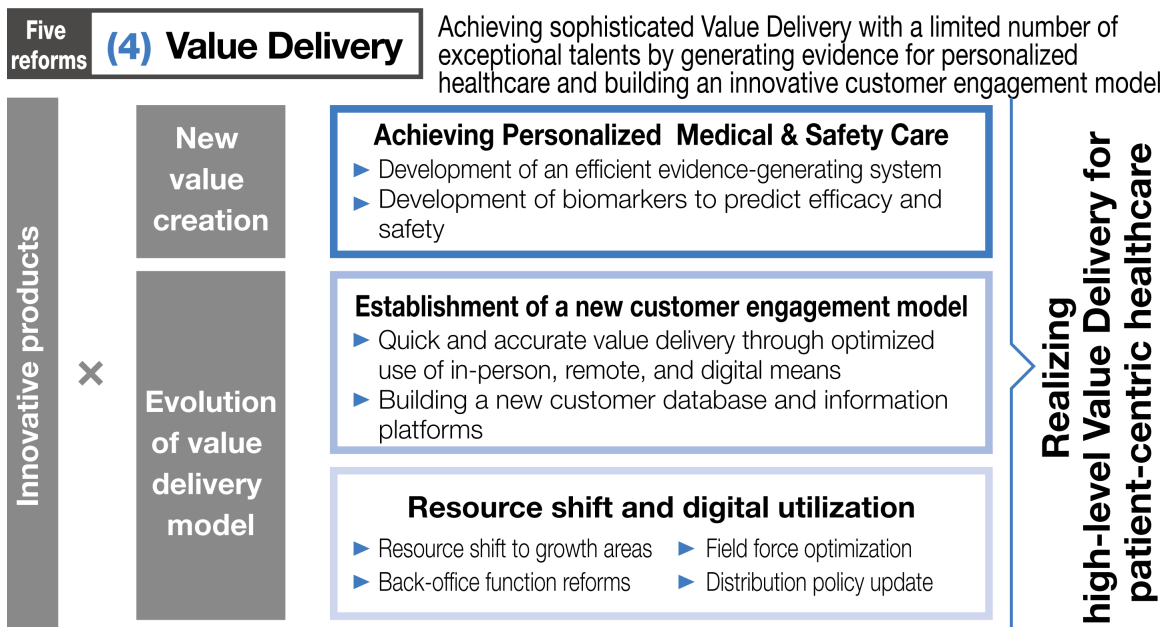
3) Pharmaceutical Technology



While the Group aims to substantially expand its R&D output, the pursuit of world-class pharmaceutical technologies that steadily commercialize innovative drug discovery will also represent an important challenge. The Group will further strengthen the collaboration between the drug discovery/early development and pharmaceutical functions, in order to advance the development of pharmaceutical technologies for drugs with a high degree of difficulty, such as mid-size molecules, through the application of leading-edge technologies. With regard to antibody drugs, which are expected to continue evolving as a core technology, the Group will continue to work to further promote technological development and to improve the speed of development.

Meanwhile, the Group will also pursue world-class cost competitiveness and cost reduction, by building next-generation plants that dramatically improve productivity by means of digital and robotics technologies, and by optimizing insourcing and outsourcing.

4) Value Delivery

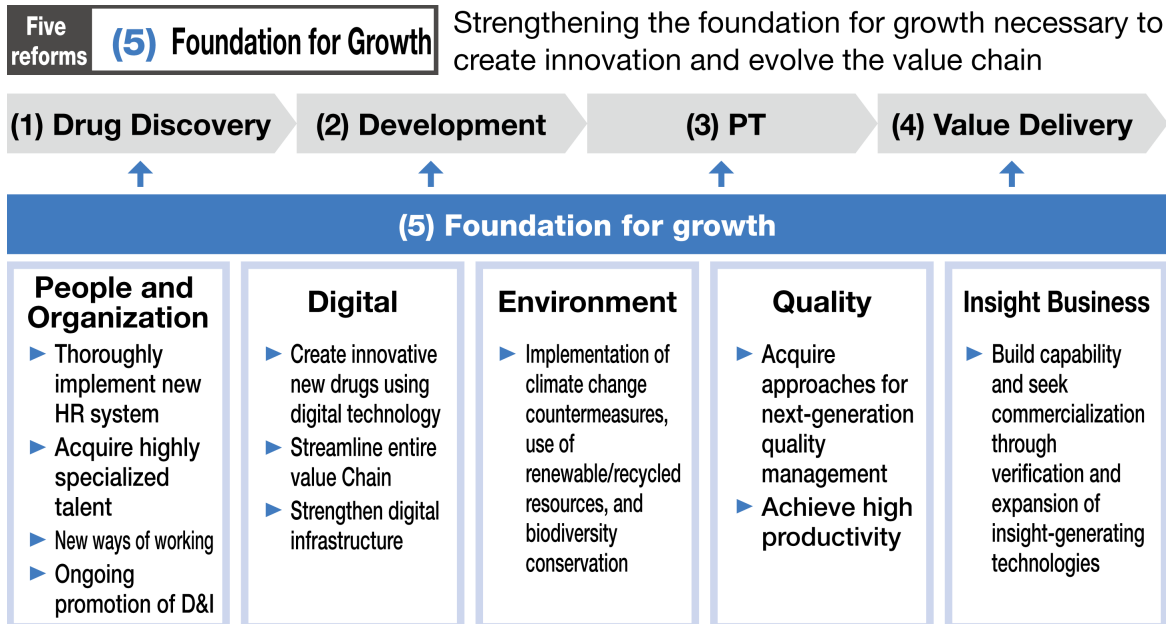


The customer contact points of pharmaceutical companies have also changed significantly owing to the development of digital tools and the impact of the spread of COVID-19. By also taking such changes into account, the Group will aim to establish an innovative customer engagement model, in order to deliver the information required by healthcare professionals and patients accurately and promptly, while ensuring a high level of expertise. Specifically, the Group will strengthen a system that is capable of providing valuable information to customers promptly and optimally, through the appropriate utilization of face-to-face, remote and digital systems, as well as suitable collaboration among the specialized functions of sales, safety and medical functions.

In line with changes in its product portfolio, the Group will also work on shifting resources by intensively allocating resources to new and growth areas.

In addition, the Group will advance the generation of evidence that promotes personalized healthcare, and also accelerate the development of biomarkers that accurately predict efficacy and safety for each patient, through the comprehensive analysis and utilization of various databases accumulated through drug discovery and development, as well as real-world data.

5) Foundation for Growth



In parallel with the reforms of each value chain, the Group will work to strengthen its company-wide foundation, which supports the generation of innovation and the realization of its growth strategy. To this end, the Group has specifically set out the following five themes, as priority areas.

“People and Organization”: Through operation of the personnel system, which commenced in 2020, the Group will promote the assignment of the right personnel to the right positions through further advances in position management and talent management, and enhance the corporate culture to encourage personnel to boldly take on challenges. The Group will also focus on the acquisition, nurturing and provision of a sufficient number of highly specialized human resources, who will be the key in implementing business strategies, such as those in the fields of digital technology and science, including data scientists. At the same time, the Group will strive to foster an innovation culture through ongoing promotion of diversity and inclusion (D&I).

“Digital”: Under “CHUGAI DIGITAL VISION 2030,” the Group will implement three basic strategies: 1. Build a digital platform for both software and hardware, while establishing a global-level IT infrastructure by integrating various in-house data and building an analysis platform in collaboration with the Roche Group; 2. Promote digitalization in all value chains; and 3. Digital transformation for drug discovery and development.

“Environment”: The Group will contribute to the realization of a sustainable global environment by setting mid-term environmental goals for the three issues identified as material: climate change countermeasures, use of renewable/recycled resources, and protection of biodiversity, with the final year set for 2030. Climate change countermeasures, which is the most critical global theme, will the Group work on over the long term, aiming to achieve its goal of zero CO₂ emissions by 2050.

“Quality”: The Group has worked to advance not only product quality, but also quality management, with respect to its responses to pharmaceutical affairs and the entire business processes. Going forward, the Group will also enhance the development and implementation of quality management methods, suitable for changing business processes, including responding to new regulations accompanying a variety of technological evolution and modality challenges, enhancing digital compliance, and developing a quality assurance system in anticipation of expanded collaboration with external parties.

“Insight Business”: The Group will accelerate initiatives to extract and utilize various insights that contribute to in-house drug discovery and development, and maximization of the value of drugs, by performing advanced analysis on the accumulated data obtained in each phase of drug discovery, development, pharmaceuticals and Value Delivery, as well as external data, including real-world data. The Group will promote these initiatives while working in cooperation with Roche Group companies, including Flatiron Health, Foundation Medicine and Roche Diagnostics.

There are currently a large number of unmet medical needs worldwide, for which no treatments yet exist or treatment satisfaction is low, and patients around the world are eagerly awaiting the emergence of effective treatments. Solving each of these unmet medical needs is the need of society, and this is also the mission of the Chugai Group, as well as an opportunity for growth as a company. With the aim of becoming “a top innovator in the healthcare industry,” as set out in the Mission Statement, the Group will continue to pursue the development of society and its own growth through innovation, by steadily implementing the five reforms formulated in the growth strategy, “TOP I 2030.”

3. Basic Approach to the Selection of Accounting Standards

The Group engages actively in international business with the aim of providing a continuous flow of innovative medical products domestically and internationally. These activities include sales of pharmaceuticals and research and development overseas. In light of this, International Financial Reporting Standards (IFRS) has been adopted from the first quarter of the fiscal year ended December 31, 2013 to improve the international comparability of financial information for investors and other users of the financial statements.

4. Consolidated Financial Statements and Major Notes

(1) Consolidated income statement and consolidated statement of comprehensive income

1) Consolidated income statement in millions of yen

	Year ended December 31	
	2021	2020
Revenues	999,759	786,946
Sales	802,836	633,314
Royalties and other operating income	196,922	153,631
Cost of sales	(338,147)	(273,465)
Gross profit	661,612	513,481
Marketing and distribution	(76,592)	(72,585)
Research and development	(137,299)	(117,850)
General and administration	(25,824)	(21,816)
Operating profit	421,897	301,230
Financing costs	(48)	(62)
Other financial income (expense)	76	(1,477)
Other expense	(2,540)	(1,504)
Profit before taxes	419,385	298,188
Income taxes	(116,390)	(83,455)
Net income	302,995	214,733
Attributable to:		
Chugai shareholders	302,995	214,733
Earnings per share		
Basic (yen)	184.29	130.66
Diluted (yen)	184.17	130.53

2) Consolidated statement of comprehensive income in millions of yen

	Year ended December 31	
	2021	2020
Net income recognized in income statement	302,995	214,733
Other comprehensive income		
Remeasurements of defined benefit plans	583	3,630
Financial assets measured at fair value through OCI	(291)	(22)
Items that will never be reclassified to the income statement	292	3,608
Financial assets measured at fair value through OCI	3	12
Cash flow hedges	(292)	(3,072)
Currency translation of foreign operations	3,022	1,467
Items that are or may be reclassified to the income statement	2,733	(1,593)
Other comprehensive income, net of tax	3,025	2,015
Total comprehensive income	306,020	216,748
Attributable to:		
Chugai shareholders	306,020	216,748

(2) Consolidated balance sheet in millions of yen

	December 31, 2021	December 31, 2020
Assets		
Non-current assets:		
Property, plant and equipment	338,841	289,218
Right-of-use assets	13,266	8,272
Intangible assets	21,974	23,880
Financial non-current assets	2,393	2,841
Deferred tax assets	56,287	47,934
Defined benefit plan assets	1,327	492
Other non-current assets	40,944	27,954
Total non-current assets	475,033	400,592
Current assets:		
Inventories	208,838	183,893
Accounts receivable	355,081	253,342
Current income tax assets	928	12
Marketable securities	204,217	166,287
Cash and cash equivalents	267,753	212,333
Other current assets	26,844	19,039
Total current assets	1,063,661	834,906
Total assets	1,538,694	1,235,498
Liabilities		
Non-current liabilities:		
Deferred tax liabilities	(7,614)	(9,166)
Defined benefit plan liabilities	(2,945)	(2,282)
Long-term provisions	(2,101)	(2,142)
Other non-current liabilities	(10,595)	(5,835)
Total non-current liabilities	(23,255)	(19,425)
Current liabilities:		
Current income tax liabilities	(86,312)	(63,171)
Short-term provisions	(2,695)	(358)
Accounts payable	(152,266)	(100,396)
Other current liabilities	(86,149)	(72,146)
Total current liabilities	(327,422)	(236,070)
Total liabilities	(350,677)	(255,495)
Total net assets	1,188,017	980,003
Equity:		
Capital and reserves attributable to Chugai shareholders	1,188,017	980,003
Total equity	1,188,017	980,003
Total liabilities and equity	1,538,694	1,235,498

(3) Consolidated statement of cash flows in millions of yen

	Year ended December 31	
	2021	2020
Cash flows from operating activities		
Cash generated from operations	470,367	340,228
(Increase) decrease in working capital	(83,122)	(64,421)
Payments made for defined benefit plans	(3,665)	(4,656)
Utilization of provisions	(656)	(26)
Other operating cash flows	776	694
Cash flows from operating activities, before income taxes paid	383,700	271,820
Income taxes paid	(104,074)	(66,785)
Total cash flows from operating activities	279,626	205,035
Cash flows from investing activities		
Purchase of property, plant and equipment	(65,969)	(57,040)
Purchase of intangible assets	(6,897)	(4,349)
Disposal of property, plant and equipment	1,042	(22)
Interest and dividends received	133	100
Purchases of marketable securities	(362,761)	(248,143)
Sales of marketable securities	325,000	211,000
Purchases of investment securities	(9,503)	(177)
Sales of investment securities	28	319
Total cash flows from investing activities	(118,927)	(98,312)
Cash flows from financing activities		
Interest paid	(48)	(34)
Lease liabilities paid	(9,031)	(8,432)
Dividends paid to Chugai shareholders	(98,644)	(91,442)
Exercise of equity compensation plans	322	440
(Increase) decrease in own equity instruments	(8)	(30)
Total cash flows from financing activities	(107,408)	(99,497)
Net effect of currency translation on cash and cash equivalents	2,128	1,166
Increase (decrease) in cash and cash equivalents	55,419	8,393
Cash and cash equivalents at January 1	212,333	203,941
Cash and cash equivalents at December 31	267,753	212,333

(4) Consolidated statement of changes in equity in millions of yen

	Attributable to Chugai shareholders					Total equity
	Share capital	Capital surplus	Retained earnings	Other reserves	Subtotal	
Year ended December 31, 2020						
At January 1, 2020	73,016	67,037	722,076	(8,143)	853,985	853,985
Net income	—	—	214,733	—	214,733	214,733
Financial assets measured at fair value through OCI	—	—	—	(9)	(9)	(9)
Cash flow hedges	—	—	—	(3,072)	(3,072)	(3,072)
Currency translation of foreign operations	—	—	—	1,467	1,467	1,467
Remeasurements of defined benefit plans	—	—	3,630	—	3,630	3,630
Total comprehensive income	—	—	218,363	(1,615)	216,748	216,748
Dividends	—	—	(91,467)	—	(91,467)	(91,467)
Equity compensation plans	186	(774)	—	—	(588)	(588)
Own equity instruments	—	1,324	—	—	1,324	1,324
Transfer from other reserves to retained earnings	—	—	121	(121)	—	—
At December 31, 2020	73,202	67,586	849,093	(9,879)	980,003	980,003
Year ended December 31, 2021						
At January 1, 2021	73,202	67,586	849,093	(9,879)	980,003	980,003
Net income	—	—	302,995	—	302,995	302,995
Financial assets measured at fair value through OCI	—	—	—	(288)	(288)	(288)
Cash flow hedges	—	—	—	(292)	(292)	(292)
Currency translation of foreign operations	—	—	—	3,022	3,022	3,022
Remeasurements of defined benefit plans	—	—	583	—	583	583
Total comprehensive income	—	—	303,578	2,442	306,020	306,020
Dividends	—	—	(98,642)	—	(98,642)	(98,642)
Equity compensation plans	—	(27)	—	—	(27)	(27)
Own equity instruments	—	664	—	—	664	664
Transfer from other reserves to retained earnings	—	—	21	(21)	—	—
At December 31, 2021	73,202	68,223	1,054,050	(7,457)	1,188,017	1,188,017

(5) Notes regarding the going concern assumption

None

(6) Notes regarding the consolidated financial statements**1) General accounting principles and significant accounting policies****a. Basis of preparation of the consolidated financial statements**

These financial statements are the annual consolidated financial statements (“Consolidated Financial Statements”) of Chugai, a company registered in Japan, and its subsidiaries (“the Group”). The common stock of Chugai is publicly traded and listed on the Tokyo Stock Exchange under the stock code “TSE: 4519.” The Consolidated Financial Statements were approved by the Board of Directors on February 3, 2022.

Roche Holding Ltd. is a public company registered in Switzerland and the parent company of the Roche Group, which discloses its results in accordance with International Financial Reporting Standards (“IFRS”). The shareholding percentage of Roche Holding Ltd. in Chugai is 59.89% (61.16% of the total number of shares issued excluding treasury stock). The Group became principal members of the Roche Group after entering into a strategic alliance in October 2002.

The Group meets all of the requirements for a “Specified Company under Designated International Financial Reporting Standards” as stipulated under Article 1-2 of the “Ordinance on Terminology, Forms, and Preparation Methods of Consolidated Financial Statements” (Ministry of Finance of Japan Ordinance No. 28, 1976, “the Ordinance”). Hence, in accordance with Article 93 of the Ordinance, the Consolidated Financial Statements have been prepared in accordance with IFRS.

The Consolidated Financial Statements are presented in Japanese yen, which is Chugai’s functional currency and amounts are rounded to the nearest ¥1 million. They have been prepared using the historical cost convention except for items that are required to be accounted for at fair value.

b. Key accounting judgments, estimates and assumptions

The preparation of the Consolidated Financial Statements requires management to make judgments, estimates, and assumptions that affect the reported amounts of revenues, expenses, assets, liabilities, and contingent amounts. Actual outcomes could differ from those management estimates. The estimates and underlying assumptions are reviewed on an on-going basis and are based on historical experience and various other factors. Revisions to estimates are recognized in the period in which the estimate is revised.

The information for judgment, estimates, and assumptions that have a material impact on the amount recognized in the Consolidated Financial Statements of the Group is principally the same for the prior fiscal year without any significant effects including the effects of COVID-19. However, there is a possibility that the epidemic situation of COVID-19 becomes a significant risk that will cause material corrections to the carrying amounts of assets and liabilities in the next fiscal year and beyond due to the uncertainties of the future changes.

c. Significant accounting policies

The Group applies the same accounting policies that were applied to the Consolidated Financial Statements of the previous fiscal year.

Although minor changes have been made to certain accounting standards, they do not have a material impact on the Group’s overall results and financial position.

d. Future new and revised standards

The Group is currently assessing the potential impacts of new standards and interpretations that will be effective from January 1, 2022 and beyond. Based on the analysis to date, the Group does not anticipate that these will have a material impact on the Group’s overall results and financial position.

2) Operating segment information

The Group has a single business of pharmaceuticals and does not have multiple operating segments. The Group's pharmaceuticals business consists of research and development of new prescription medicines and subsequent manufacturing, marketing and distribution activities. These functional activities are integrated and managed effectively.

Information on revenues by geographical area in millions of yen

	2021		2020	
	Sales	Royalties and other operating income	Sales	Royalties and other operating income
Japan	518,948	3,449	409,106	9,852
Overseas	283,888	193,473	224,209	143,779
of which Switzerland	261,734	188,483	205,180	142,403
Total	802,836	196,922	633,314	153,631

Information by major customer in millions of yen

	2021	2020
F. Hoffmann-La Roche Ltd.	450,217	347,583
Alfresa Corporation	104,690	105,066

3) Other expense

Chugai had filed the Advance Pricing Arrangement covering the certain transactions with F. Hoffmann-La Roche Ltd., to Japanese and Swiss tax authorities. In the first quarter of FY 2017, Chugai received a notice of agreement from both tax authorities which includes the instruction that the taxable income of Chugai shall be decreased by a certain amount and that of Roche shall be increased by the same amount in each fiscal year from 2016 to 2020, and if necessary, additional adjustments to the accounts shall be made in 2021.

As a result of this agreement, Chugai will transfer a part of the deducted amount of corporate tax etc., to Roche as the estimated tax payable for Roche, in accordance with the license agreement between Chugai and Roche. In addition, it has posted ¥2,540 million of adjustment from transfer pricing taxation as a settlement etc. for the amount paid in the previous fiscal years.

4) Earnings per share**Basic earnings per share**

	2021	2020
Net income attributable to Chugai shareholders (millions of yen)	302,995	214,733
Weighted average number of common stock	1,679,057,667	1,679,057,667
Weighted average number of treasury stock	(34,907,198)	(35,612,258)
Weighted average number of shares in issue	1,644,150,469	1,643,445,409
Basic earnings per share (yen)	184.29	130.66

Note: Effective July 1, 2020, Chugai implemented a three-for-one stock split of its common stock in accordance with the resolution at the meeting of the Board of Directors held on January 21, 2020. Basic earnings per share is calculated based on the assumption that the stock split was implemented at the beginning of the previous fiscal year.

Diluted earnings per share

	2021	2020
Net income attributable to Chugai shareholders (millions of yen)	302,995	214,733
Weighted average number of shares in issue	1,644,150,469	1,643,445,409
Adjustment for assumed exercise of equity compensation plans, where dilutive	1,078,764	1,637,632
Weighted average number of shares in issue used to calculate diluted earnings per share	1,645,229,233	1,645,083,041
Diluted earnings per share (yen)	184.17	130.53

Note: Effective July 1, 2020, Chugai implemented a three-for-one stock split of its common stock in accordance with the resolution at the meeting of the Board of Directors held on January 21, 2020. Diluted earnings per share is calculated based on the assumption that the stock split was implemented at the beginning of the previous fiscal year.

There were no stock options that were eliminated from the weighted average number of shares in issue used to calculate diluted earnings per share since they do not have dilutive effects.

5) Statement of cash flows**Cash flows from operating activities**

Cash flows from operating activities arise from the Group's primary activities including research and development, manufacturing and sales in the Pharmaceuticals business. These are calculated by the indirect method by adjusting the Group's operating profit for any operating income and expenses that are not cash flows (for example depreciation, amortization and impairment) in order to derive the cash generated from operations. Operating cash flows also include income taxes paid on all activities.

Cash generated from operations in millions of yen

	2021	2020
Net income	302,995	214,733
Financing costs	48	62
Other financial income (expense)	(76)	1,477
Other expense	2,540	1,504
Income taxes	116,390	83,455
Operating profit	421,897	301,230
Depreciation of property, plant and equipment	20,974	21,966
Depreciation of right-of-use assets	5,890	5,509
Amortization of intangible assets	4,004	2,901
Impairment of property, plant and equipment	—	296
Impairment of intangible assets	6,342	657
Operating expense for defined benefit plans	4,316	4,701
Operating expense for equity-settled equity compensation plans	322	325
Net (income) expense for provisions	2,589	171
Inventory write-downs	1,350	19
Other adjustments	2,683	2,454
Cash generated from operations	470,367	340,228

Cash flows from investing activities

Cash flows from investing activities are principally those arising from the Group's investments in property, plant and equipment and intangible assets. Cash flows connected with the Group's portfolio of marketable securities and other investments are also included, as are any interest and dividend payments received in respect of these securities and investments.

Interest and dividends received in millions of yen

	2021	2020
Interest received	131	97
Dividends received	3	3
Total	133	100

Cash flows from financing activities

Cash flows from financing activities are primarily dividend payments to Chugai shareholders and lease liabilities paid.

Significant non-cash transactions

There were no significant non-cash transactions (2020: none).

6) Related parties

a. Controlling shareholder

Effective from October 2002, Roche and Chugai concluded an alliance to create a leading research-driven Japanese pharmaceutical company, which was formed by the merger of Chugai and Roche's Japanese pharmaceuticals subsidiary, Nippon Roche. Through the merger, Chugai became a principal member of the Roche Group as the surviving company.

Chugai has entered into certain agreements with Roche, which are discussed below:

Basic Alliance Agreement: As part of the Basic Alliance Agreement signed in December 2001, Roche and Chugai entered into certain arrangements covering the future operation and governance of Chugai. Amongst other matters, these cover the following areas:

- The structuring of the alliance.
- Roche's rights as a shareholder.
- Roche's rights to nominate members of Chugai's Board of Directors.
- Certain limitations to Roche's ability to buy or sell Chugai's common stock.

Chugai may issue additional shares of common stock in connection with its convertible debt and equity compensation plans, and for other purposes. If this occurs, Chugai will guarantee Roche's right to maintain its shareholding percentage in Chugai by allowing Roche to exercise its pre-emptive right or other rights.

Licensing Agreements: Under the Japan Umbrella Rights Agreement signed in December 2001, Chugai has exclusive rights to market Roche's pharmaceutical products in Japan. Chugai also has right of first refusal on the development and marketing in Japan of all development compounds held by Roche.

The Rest of the World Umbrella Rights Agreement (excluding Japan and South Korea) signed in May 2002 was revised and the Amended and Restated Rest of the World Umbrella Rights Agreement (excluding Japan, South Korea and Taiwan) was signed in August 2014. Under this Agreement, Roche has the right of first refusal on the development and marketing of Chugai's development compounds in markets outside Japan, excluding South Korea and Taiwan.

Further to these agreements, Roche and Chugai have signed a series of separate agreements for certain specific products. Depending on the specific circumstances and the terms of the agreement, this may result in payments on an arm's length basis between Roche and Chugai, for any or all of the following matters:

- Upfront payments, if a right of first refusal to license a product is exercised.
- Milestone payments, dependent upon the achievement of agreed performance targets.
- Royalties on future product sales.

These specific product agreements may also cover the manufacture, supply etc. of the respective products to meet the other party's clinical and/or commercial requirements on an arm's length basis.

Research Collaboration Agreements: Roche and Chugai have entered into research collaboration agreements in the areas of small-molecule synthetic drug research and biotechnology-based drug discovery.

Dividends: The dividends distributed to Roche by Chugai in respect to its holdings of Chugai shares totaled ¥ 60,340 million (2020: ¥55,982 million).

b. Material transactions and balances with related parties**Transactions with F. Hoffmann-La Roche** in millions of yen

	2021	2020
Revenues	450,217	347,583
Purchases	219,314	137,155

Balances with F. Hoffmann-La Roche in millions of yen

	December 31, 2021	December 31, 2020
Accounts receivable	172,112	127,475
Trade accounts payable	81,648	47,201

In the fiscal year under review, the information of transactions with Genentech, Inc. is not stated due to the decreased significance of purchases. In the previous fiscal year, purchases and trade accounts payable that arose from the transactions with Genentech, Inc. were ¥50,435 million and ¥2,756 million, respectively.

c. Remuneration of key management personnel**Remuneration of members of the board and audit & supervisory board members** in millions of yen

	2021	2020
Board of directors		
— Regular remuneration	274	258
— Bonuses	169	120
— Tenure-based restricted stock compensation	78	55
— Performance-based restricted stock compensation	94	84
Total	615	516
Audit & supervisory board members		
— Regular remuneration	99	99
Total	99	99

7) Subsequent events

There were no subsequent events in the fiscal year under review.