

NOTICE: For the convenience of capital market participants, Chugai makes efforts to provide English translations of the information disclosed in Japanese, provided that the Japanese original prevails over its English translation in the case of any discrepancy found between documentation.



CHUGAI PHARMACEUTICAL CO., LTD.

A member of the Roche group

CONSOLIDATED FINANCIAL STATEMENTS (IFRS) (Non-Audited) (for the fiscal year 2022)

Name of Company: Chugai Pharmaceutical Co., Ltd. February 2, 2023
 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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Date of Annual General Meeting of Shareholders: March 30, 2023

Date of Submission of Marketable Securities Filings: March 30, 2023

Date on which Dividend Payments to Commence: March 31, 2023

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 2022 (January 1, 2022–December 31, 2022)

(1) Consolidated operating results

	Revenues	% change	Operating profit	% change	Net income	% change
FY ended Dec. 2022	¥1,259,946 million	26.0	¥533,309 million	26.4	¥374,429 million	23.6
FY ended Dec. 2021	¥999,759 million	27.0	¥421,897 million	40.1	¥302,995 million	41.1

	Net income attributable to Chugai shareholders	% change	Total comprehensive income	% change
FY ended Dec. 2022	¥374,429 million	23.6	¥373,935 million	22.2
FY ended Dec. 2021	¥302,995 million	41.1	¥306,020 million	41.2

	Earnings per share (Basic)	Earnings per share (Diluted)
FY ended Dec. 2022	¥227.64	¥227.57
FY ended Dec. 2021	¥184.29	¥184.17

	Ratio of net income to equity attributable to Chugai shareholders	Ratio of operating profit to revenues
FY ended Dec. 2022	28.7%	42.3%
FY ended Dec. 2021	28.0%	42.2%

(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, 2022	¥1,869,758 million	¥1,424,387 million	¥1,424,387 million	76.2%	¥865.88
As of Dec. 31, 2021	¥1,538,694 million	¥1,188,017 million	¥1,188,017 million	77.2%	¥722.50

(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, 2022	¥244,112 million	¥(145,994) million	¥(145,641) million	¥222,169 million
FY ended Dec. 31, 2021	¥279,626 million	¥(118,927) million	¥(107,408) million	¥267,753 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. 2021	—	¥30.00	—	¥46.00	¥76.00
FY ended Dec. 2022	—	¥38.00	—	¥40.00	¥78.00
FY ending Dec. 2023 (Forecast)	—	¥40.00	—	¥40.00	¥80.00

	Total dividends (annual)	Dividend payout ratio (consolidated)	Ratio of dividends to equity attributable to Chugai shareholders (consolidated)
FY ended Dec. 2021	¥124,965 million	41.2%	11.5%
FY ended Dec. 2022	¥128,310 million	34.3%	9.8%
FY ending Dec. 2023 (Forecast)		—%	

3. Consolidated forecasts on Core basis for FY 2023 (January 1, 2023–December 31, 2023)

	Core revenues	% change	Core operating profit	% change	Core net income	% change
FY ending Dec. 2023 (Forecast)	¥1,070,000 million	(8.4)	¥415,000 million	(8.1)	¥306,000 million	(3.7)
FY ended Dec. 2022 (Results)	¥1,167,811 million	+16.8	¥451,676 million	+4.0	¥317,738 million	+2.0

	Core earnings per share		Core dividend payout ratio %
FY ending Dec. 2023 (Forecast)	¥186.00	(3.7)	43.0
FY ended Dec. 2022 (Results)	¥193.11	+2.0	40.4

Notes: 1. Percentages shown for Core 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.

3. Starting from FY 2023, Chugai will exclude income from disposal of product rights from revenues. In conjunction with this change, the results for FY 2022 have been restated accordingly.

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)
- (b) Number of treasury stock at the end of the period
- (c) Average number of shares issued during the period

As of Dec. 31, 2022	1,679,057,667	As of Dec. 31, 2021	1,679,057,667
As of Dec. 31, 2022	34,037,098	As of Dec. 31, 2021	34,739,943
FY ended Dec. 31, 2022	1,644,797,728	FY ended Dec. 31, 2021	1,644,150,469

Note: For an explanation of the number of shares used for computing earnings per share (consolidated), please refer to “Earnings per share” on page 25 of the attached document.

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”). Core results are the results after adjusting non-recurring items recognized by Chugai to IFRS results. Chugai’s recognition of non-recurring items may differ from that of Roche due to the difference in the scale of operations, the scope of business and other factors. Core results are used by Chugai as an indicator for managing internal business performance, explaining the status of recurring profits both internally and externally, and as the basis for payment-by-results such as shareholder returns. 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 10, “Basic profit distribution principles and dividends for the fiscal year under review and the following fiscal year” on page 11, and “Management Principles and Goals” on page 12 - 17 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 2, 2023, Thursday (Japan time).

The English-translated scripts of the presentation and the Q&A will be posted on the website within two business days.

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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
	2022	2021	
Core results			
Revenues	1,168.0	999.8	+16.8
Sales	1,039.2	802.8	+29.4
Royalties and other operating income	128.8	196.9	(34.6)
Cost of sales	(475.0)	(335.5)	+41.6
Gross profit	693.0	664.3	+4.3
Marketing and distribution	(76.7)	(75.8)	+1.2
Research and development	(143.7)	(129.8)	+10.7
General and administration	(20.9)	(24.6)	(15.0)
Operating profit	451.7	434.1	+4.1
Net income	317.7	311.5	+2.0
IFRS results			
Revenues	1,259.9	999.8	+26.0
Operating profit	533.3	421.9	+26.4
Net income	374.4	303.0	+23.6

Consolidated financial highlights (IFRS results)

Revenues for the fiscal year under review were ¥1,259.9 billion (an increase of 26.0% year on year), operating profit for the fiscal year under review was ¥533.3 billion (an increase of 26.4% year on year), and net income for the fiscal year under review was ¥374.4 billion (an increase of 23.6% year on year). These results include non-Core items, such as amortization of intangible assets of ¥1.7 billion, impairment loss of intangible assets of ¥0.6 billion, and restructuring expenses, etc. of ¥6.8 billion, as well as the income and other related items which totaled ¥90.7 billion associated with the settlement agreement between Chugai and Alexion Pharmaceuticals, Inc., 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 ¥1,168.0 billion (an increase of 16.8% year on year), due to a significant increase in sales, despite major decreases in royalties and other operating income.

Of revenues, sales were ¥1,039.2 billion (an increase of 29.4% year on year). Domestic sales grew over the previous fiscal year primarily due to the steady market penetration of the new products Evrysdi, Polivy, Enspryng and Vabysmo, the favorable sales of the mainstay products Hemlibra and Kadcyla, 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 significantly compared to the previous fiscal year due to the major increase in the exports of Hemlibra and Actemra, despite a decrease in the export of Alecensa to Roche. Royalties and other operating income amounted to ¥128.8 billion (a decrease of 34.6% year on year), due to a significant decrease in royalty income from initial shipments of Hemlibra. Furthermore, cost to sales ratio was 45.7%, a 3.9 percentage point rise year on year, reflecting a change in the product mix and other factors. As a result, gross profit amounted to ¥693.0 billion (an increase of 4.3% year on year).

Operating expenses were ¥241.3 billion (an increase of 4.8% year on year). Marketing and distribution expenses were ¥76.7 billion (an increase of 1.2% year on year) due to the effects of foreign exchange and other factors. Research and development expenses amounted to ¥143.7 billion (an increase of 10.7% year on year) due to an increase in expenses associated with the progress of development projects, the effects of foreign exchange and other factors. General and administration expenses amounted to ¥20.9 billion (a decrease of 15.0% year on year) due to decreases in various expenses, as well as recognizing gain on sale of property, plant and equipment. As a result, operating profit was ¥451.7 billion (an increase of 4.1% year on year) and net income was ¥317.7 billion (an increase of 2.0% year on year).

Meanwhile, compared to the full year forecast announced on February 3, 2022, revenues increased by 1.6% to ¥1,168.0 billion, due to royalties and profit-sharing income exceeding the forecast, as a result of the effects of foreign exchange and other factors, in addition to the favorable performance of domestic sales. The cost to sales ratio was 45.7%, a rise by 1.1 percentage points over the full year forecast, reflecting the effects of foreign exchange, etc. Operating expenses decreased by 3.5% to ¥241.3 billion compared to the full year forecast, due to decreases in research and development expenses and general and administration expenses. As a result, Core operating profit surpassed the full year forecast by 2.7% and reached ¥451.7 billion.

With regard to the effects of the changing situation in Russia and Ukraine on operating performance for the fiscal year under review, while Chugai is not directly engaged in any business activities and has no contract manufacturers or suppliers of raw materials in the countries concerned, certain costs and expenses have increased due to soaring energy and other prices stemming from the changing situation in these countries. Furthermore, while there have been some impacts on the progress of certain trials led by Roche in these countries and their neighboring countries, the impact on research and development activities as a whole has been limited.

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. Chugai's recognition of non-recurring items may differ from that of Roche due to the difference in the scale of operations, the scope of business and other factors. 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 for Consolidated Financial Results for Fiscal Year 2022. 12 (IFRS), dated February 2, 2023, on page 1, entitled "Reconciliation of IFRS results to Core results."

Sales breakdown in billions of yen

	Year ended December 31		% change
	2022	2021	
Sales	1,039.2	802.8	+29.4
Domestic sales	654.7	518.9	+26.2
Oncology	256.0	261.5	(2.1)
Specialty*	398.6	257.4	+54.9
Overseas sales	384.6	283.9	+35.5

Domestic sales

Domestic sales were ¥654.7 billion (an increase of 26.2% year on year) due to the favorable market penetration of mainstay products and new products, while sales were significantly affected by the NHI drug price revisions and the market penetration of generic drugs.

Oncology products sales were ¥256.0 billion (a decrease of 2.1% year on year). Thanks to the favorable market penetration of the new product Polivy (an antimicrotubule binding anti-CD79b monoclonal antibody, anti-cancer agent) due to an additional indication, the strong sales of Kadcyla (an anti-HER2 antibody-tubulin polymerization inhibitor conjugate), and the increase in the number of tests provided by the Foundation Medicine genomic mutation analysis program**, sales increased. Meanwhile, sales of Avastin (an anti-VEGF humanized monoclonal antibody, anti-cancer agent) and Herceptin (an anti-HER2 humanized monoclonal antibody, anti-cancer agent) declined affected by the NHI drug price revisions and market penetration of generic drugs, and sales of Tecentriq (an anti-PD-L1 humanized monoclonal antibody, anti-cancer agent) also declined, primarily due to a re-pricing for market expansion in August 2021.

Specialty products sales were ¥398.6 billion (an increase of 54.9% year on year). Despite a sales decline of products including Edirof (an osteoporosis agent) and Mircera (a long-acting erythropoiesis stimulating agent) due to NHI drug price revisions and market penetration of generic drugs, sales of the mainstay product Hemlibra (blood coagulation factor VIII substitute) were favorable. As for the new products, recognizing a significant increase in 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 the favorable market penetration of Evrysdi (spinal muscular atrophy agent), Enspryng (a pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody) and Vabysmo (an ophthalmic VEGF/Ang-2 inhibitor, anti-VEGF/anti-Ang-2 humanized bispecific monoclonal antibody). In addition, regarding Mitchga (an anti-IL-31 receptor A humanized monoclonal antibody), a new product launched in August 2022 by Maruho Co., Ltd. ("Maruho") for the indication of itching associated with atopic dermatitis, sales were recognized for offering this product to Maruho.

Meanwhile, compared to the full year forecast announced on February 3, 2022, domestic sales increased by 1.3% to ¥654.7 billion, due to the increased sales of Ronapreve, Evrysdi, Kadcyła, Vabysmo, etc.

* “Primary” used as the name of disease area is replaced with “Specialty” from July 2022.

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

Overseas sales

Overseas sales amounted to ¥384.6 billion (an increase of 35.5% year on year), far exceeding that of the previous fiscal year. The export of Hemlibra to Roche significantly increased to ¥191.1 billion (an increase of 70.6% year on year), as export at a regular shipping price got underway, despite a decrease in the export of Alecensa (an ALK inhibitor, anti-cancer agent) to Roche compared to the previous fiscal year. In addition, sales of Actemra, which was approved in Europe to treat patients with severe COVID-19 and in the US as a treatment for COVID-19 in hospitalized adults were favorable, increasing to ¥126.2 billion (an increase of 26.1% year on year). Furthermore, sales of Ediroł launched in China in July 2022 were ¥0.1 billion.

Meanwhile, compared to the full year forecast announced on February 3, 2022, overseas sales decreased by 0.2% to ¥384.6 billion, due to manufacturing delays of Actemra for export to Roche, despite the increased sales caused by currency exchange and other factors.

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 China 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 ¥143.7 billion (an increase of 10.7% year on year), and the ratio of R&D expenses to revenues was 12.3%.

Progress made in R&D activities during the period from January 1, 2022 to December 31, 2022 was as follows.

Oncology

- We obtained approval in March 2022 for the combination therapy of HER2 dimerization inhibitory humanized monoclonal antibody RG1273 (Product name: Perjeta) and anti-HER2 humanized monoclonal antibody RG597 (Product name: Herceptin) for the additional indication of advanced or recurrent HER2-positive colon cancer or rectal cancer not amenable to curative resection that has progressed after cancer chemotherapy.
- We obtained approval for an engineered anti-PD-L1 monoclonal antibody RG7446 (Product name: Tecentriq) for the additional indication of non-small cell lung cancer (NSCLC) (adjuvant) in May 2022. We decided to discontinue the development for ovarian cancer (1st Line) and renal cell carcinoma (adjuvant) in consideration of the results of global Phase III studies IMagyn050 and IMmotion010, respectively.
- Based on public knowledge-based applications, we obtained the partial change approval for a recombinant human G-CSF Neutrogin for the indication of relapsed or refractory acute myeloid leukemia in combination with anticancer agents in June 2022.
- We obtained approval for an anti-CD79b antibody-drug conjugate RG7596 (Product name: Polivy) for the additional indication of previously untreated diffuse large B-cell lymphoma (DLBCL) in August 2022.
- We filed for a glycoengineered type II anti-CD20 monoclonal antibody RG7159 (Product name: Gazyva) for the treatment of chronic lymphocytic leukemia in March 2022, and obtained approval for the additional indication of CD20-positive chronic lymphocytic leukemia (including small lymphocytic lymphoma) in December 2022.
- We filed for anti-HER2 humanized monoclonal antibody / HER2 dimerization inhibitory humanized monoclonal antibody RG6264 (fixed-dose subcutaneous combination) for the treatment of HER2-positive breast cancer, and HER2-positive colorectal cancer that has progressed after chemotherapy in September 2022.
- We started global Phase III study for an ALK inhibitor AF802/RG7853 (Product name: Alecensa) for the maintenance treatment of NSCLC (stage III) after chemoradiotherapy in November 2022.
- We started global Phase III study for an anti-TIGIT human monoclonal antibody RG6058 for the treatment of non-squamous NSCLC (1st Line), in combination with RG7446 in November 2022. We decided to discontinue the development for small cell lung cancer (SCLC) (1st Line) in combination with RG7446, in consideration of the results of global Phase III study SKYSCRAPER-02.
- We started domestic Phase II study for a RET inhibitor RG6396 for the treatment of NSCLC (2nd Line) in June 2022. We also started global Phase II study for the treatment of solid tumors in October 2022.
- We started Phase I study for an anti-CD20/CD3 bispecific antibody RG7828 for the treatment of follicular lymphoma (3rd Line) in March 2022. We also started global Phase III study for the treatment of relapsed or refractory aggressive B-cell non-Hodgkin’s lymphoma, in combination with Polivy in October 2022.
- We started Phase I study for a KRAS G12C inhibitor RG6330 and a SHP2 inhibitor RG6433 for the treatment of solid tumors in September 2022.
- We started Phase I study for an anti-FcRH5/CD3 bispecific antibody RG6160 for the treatment of relapsed or refractory multiple myeloma in November 2022.
- We decided to discontinue the development of AMY109 for solid tumors in consideration of the results of the Phase I study.

Immunology

- We obtained approval for a humanized anti-human IL-6 receptor monoclonal antibody MRA/RG1569 (Product name: Actemra) for the additional indication of SARS-CoV-2 pneumonia (limited to patients requiring oxygen intervention) in January 2022. The U.S. Food and Drug Administration (FDA) accepted the supplemental Biologics License Application (sBLA) for the treatment of COVID-19 in hospitalized adults who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) in April 2022 and approved for the above indication in December 2022. An application for regulatory approval for systemic sclerosis-associated interstitial lung disease was submitted to the European Medicines Agency (EMA) in August 2022.
- We started domestic Phase III study for a glycoengineered type II anti-CD20 monoclonal antibody RG7159 (Product name: Gazyva) for the treatment of lupus nephritis in June 2022.
- We started Phase I study for an anti-HLA-DQ2.5/gluten peptides multispecific antibody DONQ52 for the treatment of celiac disease in September 2022.
- We started Phase I study for RAY121 for the treatment of autoimmune diseases in October 2022.
- We decided to discontinue the development of a human IL-22 fusion protein RG7880 for inflammatory bowel disease in consideration of the results of overseas study conducted by Roche.

Neuroscience

- We obtained approval for an anti-CD20 monoclonal antibody Rituxan for the additional indication of the prevention of recurrence of neuromyelitis optica spectrum disorder (including neuromyelitis optica) in June 2022.
- We started global Phase III studies for a pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody SA237/RG6168 (Product name: Enspryng) for the treatment of myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD) and autoimmune encephalitis (AIE) in August and September 2022, respectively.
- We started global Phase II/III study for an anti-latent myostatin sweeping antibody GYM329/RG6237 for the treatment of spinal muscular atrophy, in combination with RG7916 in June 2022.

Hematology

- We obtained approval for an anti-factor IXa/X bispecific antibody ACE910/RG6013 (Product name: Hemlibra) for the additional indication of acquired hemophilia A in June 2022.
- We started Phase II study for an anti-C5 recycling antibody SKY59/RG6107 for the treatment of sickle cell disease in March 2022. The National Medical Products Administration (NMPA) of People's Republic of China accepted an application for regulatory approval for paroxysmal nocturnal hemoglobinuria (PNH) and granted priority review in the third quarter of 2022.

Ophthalmology

- We obtained approval for an anti-VEGF/anti Ang-2 bispecific antibody RG7716 (Product name: Vabysmo) for the indications of age-related macular degeneration associated with subfoveal choroidal neovascularization and diabetic macular edema in March 2022 and launched in May 2022.
- We started domestic Phase I/II study for a humanized anti-VEGF monoclonal antibody fragment (Fab) RG6321 [PDS (Port Delivery System with ranibizumab)] for the treatment of neovascular age-related macular degeneration and diabetic macular edema in March 2022.

Other Diseases

- We launched activated vitamin D3 agent ED-71 (Product name: Ediolol) in China for the treatment of postmenopausal osteoporosis in July 2022.
- We decided to discontinue the development of an anti-FGFR1/KLB bispecific antibody RG7992 for non-alcoholic steatohepatitis in consideration of the results of overseas study conducted by Roche.

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, 2022	December 31, 2021	Change in amount
Net operating assets (NOA) and Net assets			
Net working capital	551.6	370.1	181.5
Long-term net operating assets	447.8	402.4	45.4
Net operating assets (NOA)	999.3	772.6	226.7
Net cash	503.1	472.0	31.1
Other non-operating assets – net	(78.1)	(56.5)	(21.6)
Total net assets	1,424.4	1,188.0	236.4
Consolidated balance sheet (IFRS basis)			
Total assets	1,869.8	1,538.7	331.1
Total liabilities	(445.4)	(350.7)	(94.7)
Total net assets	1,424.4	1,188.0	236.4

Net operating assets (NOA) at December 31, 2021 were ¥999.3 billion, an increase of ¥226.7 billion since the end of the previous fiscal year. Of NOA, net working capital was ¥551.6 billion (an increase of ¥181.5 billion since the end of the previous fiscal year), due to an increase in accounts receivable from the sales of Ronapreve and others. Long-term net operating assets increased by ¥45.4 billion to ¥447.8 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 ¥31.1 billion from the end of the previous fiscal year to ¥503.1 billion. Other non-operating assets – net decreased by ¥21.6 billion from the end of the previous fiscal year to ¥(78.1) billion due mainly to an increase in foreign exchange contracts liabilities.

As a consequence, total net assets were ¥1,424.4 billion (an increase of ¥236.4 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 10, 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
	2022	2021	
Free cash flows			
Operating profit - IFRS basis	533.3	421.9	+26.4
Operating profit, net of operating cash adjustments	570.6	466.4	+22.3
Operating free cash flows	308.4	301.4	+2.3
Free cash flows	166.4	189.4	(12.1)
Net change in net cash	31.1	93.4	(66.7)
Consolidated statement of cash flows (IFRS basis)			
Cash flows from operating activities	244.1	279.6	(12.7)
Cash flows from investing activities	(146.0)	(118.9)	+22.8
Cash flows from financing activities	(145.6)	(107.4)	+35.6
Net change in cash and cash equivalents	(45.6)	55.5	—
Cash and cash equivalents at December 31	222.2	267.8	(17.0)

Operating profit, net of operating cash adjustments, amounted to ¥570.6 billion (an increase of 22.3% 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 ¥308.4 billion (an increase of 2.3% year on year) due to an increase in operating profit, despite an increase in net working capital, etc. of ¥183.3 billion, as well as expenditures of ¥62.6 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” on the previous page.

Free cash flows were a net cash inflow of ¥166.4 billion (a decrease of 12.1% year on year) due mainly to income taxes paid of ¥152.1 billion from operating free cash flows.

The net change in net cash calculated by subtracting dividends paid of ¥138.2 billion, etc. from free cash flows was an increase of ¥31.1 billion.

The net change in cash and cash equivalents, excluding changes in marketable securities and interest-bearing debt, was a net cash outflow of ¥45.6 billion. The cash and cash equivalents balance at the end of this period amounted to ¥222.2 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 11, entitled “Cash flows.”

Cash flow related indicators

	Year ended December 31			
	2022	2021	2020	2019
Ratio of equity attributable to Chugai shareholders (%)	76.2	77.2	79.3	80.6
Ratio of equity attributable to Chugai shareholders on a market basis (%)	296.3	399.1	732.2	521.2
Interest-coverage ratio (times)	4,180.2	5,861.7	6,067.7	7,537.5

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-coverage ratio: $\text{Cash flows} / \text{Interest payments}$

Notes:

1. All of the figures in the aforementioned indicators were calculated on a consolidated basis.
2. 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).
3. Cash flows from operating activities in the consolidated statement of cash flows were used as cash flows in the calculations above.
4. 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 ¥138/CHF, ¥141/EUR, ¥131/USD, and ¥98/SGD.

Furthermore, Chugai will implement the following changes in the financial statements effective from the next fiscal year (FY2023).

- “Royalties and other operating income”, which has previously been reported under revenues will be changed to “other revenues”, while income from disposal of product rights will be excluded therefrom.
- “Other operating income (expense)”, a new category on the same level as research and development expenses, marketing and distribution expenses, and general and administration expenses will be added. “Other operating income (expense)” will include income from disposal of product rights, which will be excluded from revenues as described above, as well as revenues and expenses associated with operating activities that have previously been included and presented under general and administration expenses, such as gain (loss) on sale of land and buildings, etc., which could not be classified in any of the functional expense categories.
- Marketing and distribution expenses and general and administration expenses will be combined and presented as “selling, general and administration expenses”.

These changes shall have no effect on the items from operating profit through net income, earnings per share and the concept of the Core basis. Additionally, year-on-year comparisons in “Outlook for the fiscal year” stated below represent comparisons upon also applying the aforementioned change in the presentation of income from disposal of product rights to the financial statements of the current fiscal year, the object of the comparison.

Outlook for the fiscal year**Core revenues**

Core revenues are expected to decrease to ¥1,070.0 billion (a decrease of 8.4% year on year).

Of core revenues, domestic sales are expected to decrease to ¥541.7 billion (a decrease of 17.3% year on year), due to the decrease in the sales in Ronapreve for supply to the government, in addition to the negative impact from intensifying competition associated primarily with launches of biosimilars and generics as well as NHI drug price revisions, despite the sales growth in new products such as Polivy, Vabysmo, Enspryng, etc., and the mainstay products including Tecentriq and Hemlibra. Sales from the supply of Ronapreve to the government are expected to reach ¥81.2 billion (a decrease of 60.1% year on year), while domestic sales excluding Ronapreve are favorably expected to be ¥460.5 billion (an increase of 2.1% year on year).

Overseas sales are expected to decrease to ¥378.3 billion (a decrease of 1.6% year on year), due to the decreases in sales of Actemra and Hemlibra, despite the sales growth of Alecensa. The export of Hemlibra to Roche is expected to be ¥181.5 billion (a decrease of 5.0% year on year), due to the decrease in export volume reflecting the Roche Group’s optimization of its inventory levels and the effects of the declining Swiss franc-denominated export price from Chugai to Roche as result of the global market penetration of Hemlibra, despite the positive effects on sales of the depreciating yen.

Other revenues are expected to reach ¥150.0 billion (an increase of 16.6% year on year). Royalty and profit-sharing income are forecasted to increase to ¥133.0 billion (an increase of 8.0% year on year), due to an increase in income related to Hemlibra in addition to an increase in one-time income.

Core Operating Profit / Core EPS

Gross profit is expected to decrease to ¥665.0 billion (a decrease of 4.0% year on year), with the assumption that the cost to sales ratio is 44.0%, which is a 1.7 percentage point improvement year on year, due to a change in the product mix, etc., in addition to the above outlook on Core revenues.

Research and development expenses are expected to increase to ¥165.0 billion (an increase of 14.8% year on year) due to investments into drug discovery/early development including the operation of Chugai Life Science Park Yokohama, the progress of development projects, etc., and selling, general and administration expenses are expected to increase slightly by 1.2% year on year to ¥100.0 billion. Other operating income (expense) is expected to be ¥15.0 billion of income (FY 2022: ¥1.4 billion of income) mainly due to the impact of income from disposal of product rights.

Core operating profit is expected to be ¥415.0 billion (a decrease of 8.1% year on year) and Core net income is expected to be ¥306.0 billion (a decrease of 3.7% year on year). Core EPS is forecasted to be ¥186.00 (a decrease of 3.7% year on year).

(Billions of yen)

	Outlook for FY 2023	% change
Core revenues	1,070.0	(8.4)
Sales	920.0	(11.5)
Core operating profit	415.0	(8.1)
Core net income	306.0	(3.7)

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, 2022, Chugai achieved the highest results in the past, which resulted in Core EPS increasing by 2.0% 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, 2022 are planned to be ¥40 per share. As a result, the annual dividend per share will be ¥78 per share, and the Core dividend payout ratio is 40.4% (an average of 42.0% for the past five years).

For the following fiscal year ending December 31, 2023, Chugai expects annual dividends of ¥80 including interim dividends of ¥40. As a result, the Core dividend payout ratio for 2023 is expected to be 43.0% (41.8% on a five-year average basis).

	Amount decided	Latest forecast for dividend (February 3, 2022)	Actual in the previous fiscal year (ended Dec. 31, 2021)
Record date	December 31, 2022	December 31, 2022	December 31, 2021
Year-end dividends per share	¥40.00	¥38.00	¥46.00
Total dividends	¥65,801 million	—	¥75,639 million
Effective date	March 31, 2023	—	March 30, 2022
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.

Chugai has formulated a growth strategy toward 2030, "TOP I 2030" (described later), and is working to achieve the goals of "Double R&D output" and "Launch global in-house products every year." In promoting "TOP I 2030," Chugai has determined to stop formulating medium-term (three years) management plans, and instead it sets and manages goals (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, Chugai 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. Chugai will disclose the status of progress of its medium- to long-term business activities, by explaining the progress of medium-term milestones and the outlook for R&D pipelines, and indicate the path for achieving these objectives. Chugai also plans to continue disclosing single-year 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. There are also many diseases that currently have no cure. Meanwhile, 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 steadily 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 its unique strengths in science and technology and its strategic alliance with Roche. The Group concentrates resources on in-house drug discovery and continuously generates innovative R&D projects, through the business model that leverages the Roche global platform and achieves a high level of productivity in the late-stage development and sales of its own products, while securing a stable revenue foundation on the Japanese market through Roche's fully stocked pipeline. 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).

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 to the above-mentioned challenges to realize sustainable medical care, Chugai has designated the global environment, human rights, social contribution, governance, ethics and compliance, and supply chain management as material issues to be addressed and will continue to strive for their 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

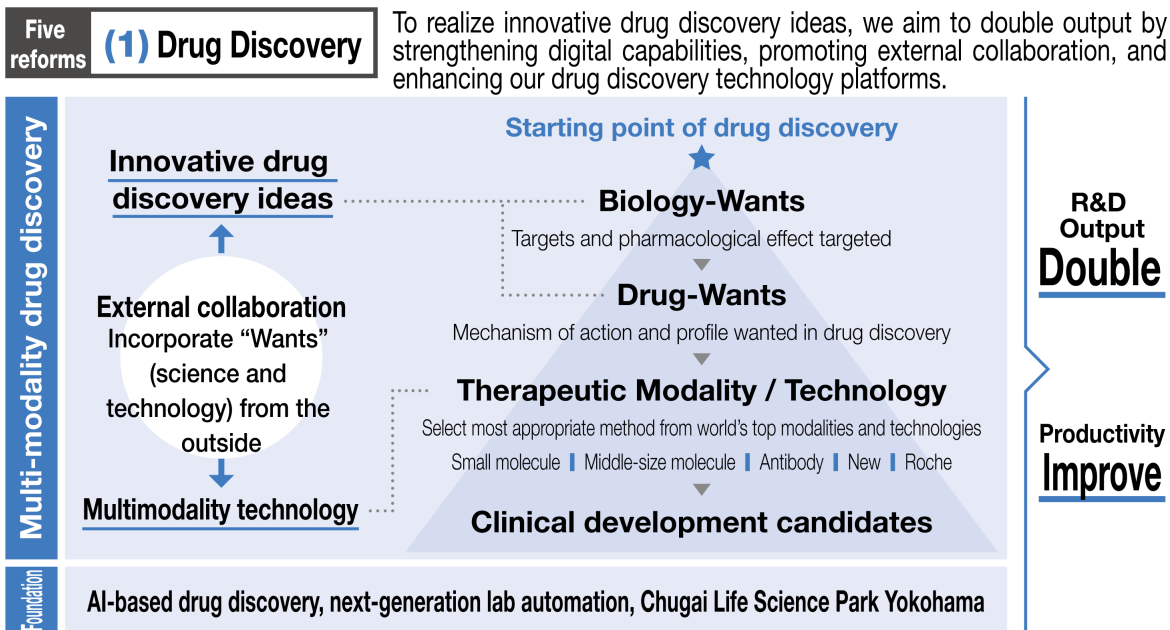
The twin pillars of “TOP I 2030” consist of “Global First-Class Drug Discovery” and “Futuristic Business Model.”

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.

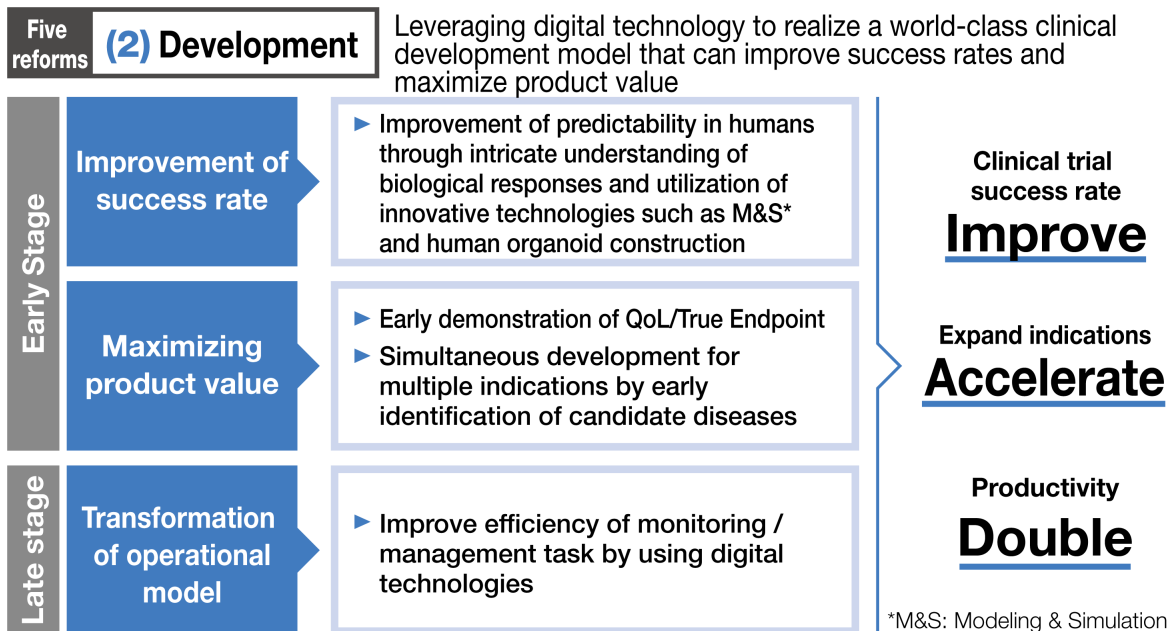
As specific initiatives, the Group has set forth “five reforms” in line with its value chain to realize the twin pillars of the strategy. These reforms comprise “Drug Discovery,” “Development,” “Pharmaceutical Technology,” “Value Delivery” and “Foundation for Growth.”

1) Drug Discovery



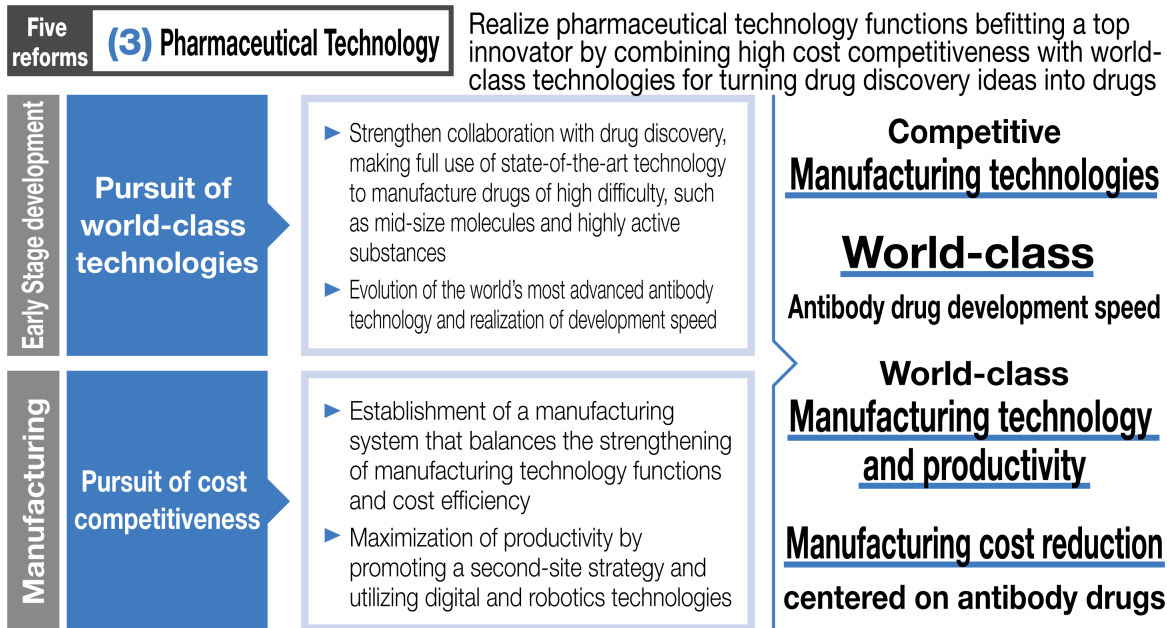
In “TOP I 2030,” the Group will aim to further strengthen its drug discovery technology foundation, in order to materialize original drug discovery ideas based on its accumulated strengths in drug discovery, including protein engineering technology. In addition, the Group will concentrate resources on 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.

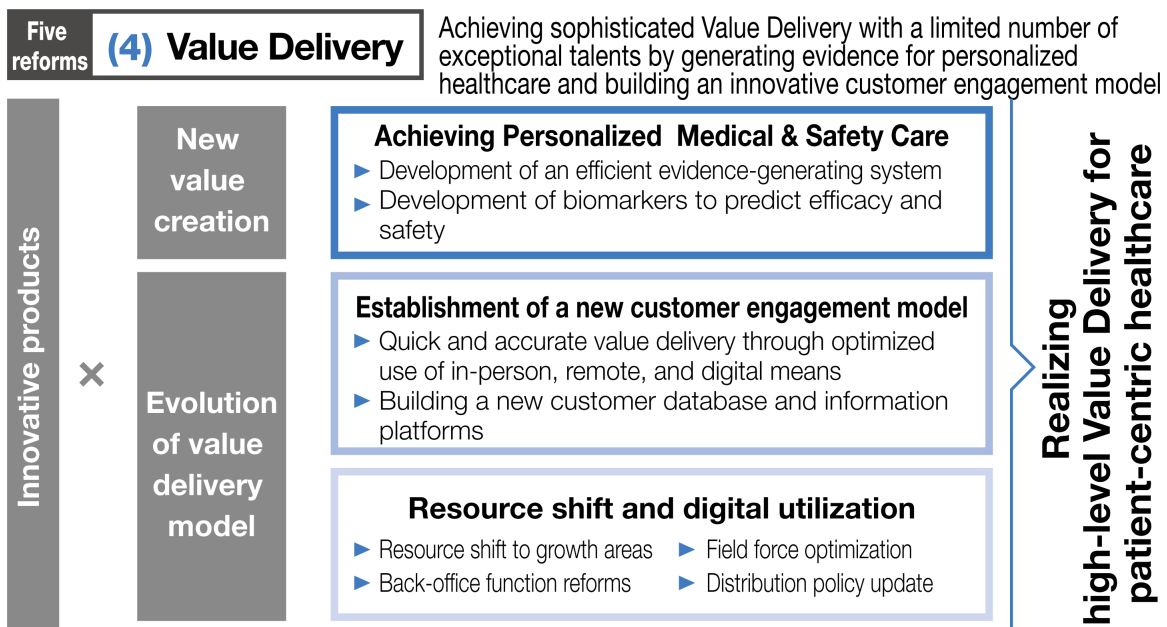
3) Pharmaceutical Technology



When aiming to substantially expand our 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

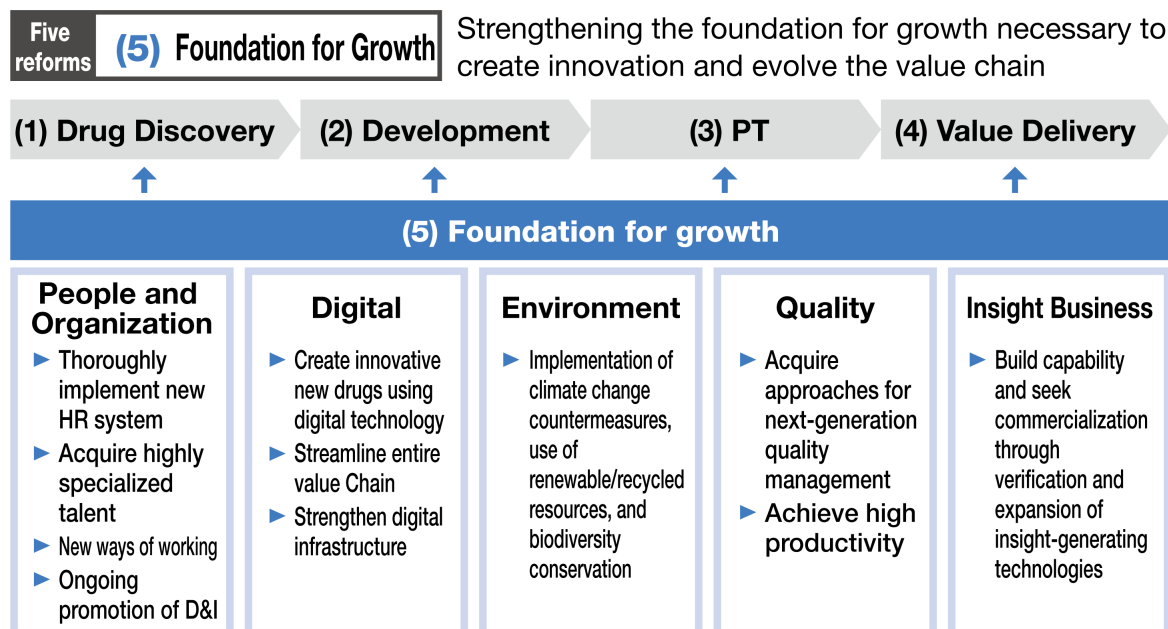


The customer contact points of pharmaceutical companies have also changed significantly owing to the development of digital tools and the impact of the spread of COVID-19. By also taking such changes into account, the Group will aim to establish an innovative customer engagement model, in order to deliver 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, enhance the corporate culture to encourage personnel to boldly take on challenges and engage in dialogues, and 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 a culture that creates innovation through ongoing promotion of diversity and inclusion (D&I).

“Digital”: Under “CHUGAI DIGITAL VISION 2030,” the Group will focus on innovative drug discovery by applying digital technologies, while promoting DX in each part of the value chain to improve efficiency. To this end, the Group will 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.

“Environment”: The Group will contribute to the realization of a sustainable global environment by setting Mid-Term Environmental Goals 2030 for the three issues identified as material: climate change countermeasures, use of renewable/recycled resources, and protection of biodiversity, and implementing advanced initiatives to achieve them. For climate change countermeasures in particular, the Group will work on long-term programs aimed at achieving the goal of zero CO₂ emissions by 2050.

“Quality”: In addition to measures implemented thus far to ensure product quality, the Group is also working to advance quality management across all business processes and in our responses to pharmaceutical affairs. Furthermore, the Group will also step up the development and implementation of quality management methods that balance both quality and efficiency suited to changing business processes, including responding to regulatory affairs matters that address challenges brought about by new modalities and diverse technological evolution, enhancing digital compliance, and developing a quality assurance system in anticipation of expanded collaboration with external parties.

“Insight Business”: Working in partnership with other Roche Group companies, the Group will collect external data, including real-world data (RWD) and data obtained at each stage of drug discovery, development, pharmaceutical technology, and value delivery, and perform advanced analysis to extract and utilize various insights that contribute to in-house drug discovery and development and maximizing the value of pharmaceuticals.

As stated above, 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, “TOPI 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	
	2022	2021
Revenues	1,259,946	999,759
Sales	1,039,247	802,836
Royalties and other operating income	128,784	196,922
Other revenue	91,915	—
Cost of sales	(476,251)	(338,147)
Gross profit	783,695	661,612
Marketing and distribution	(77,149)	(76,592)
Research and development	(149,626)	(137,299)
General and administration	(23,611)	(25,824)
Operating profit	533,309	421,897
Financing costs	(61)	(48)
Other financial income (expense)	52	76
Other expense	(2,134)	(2,540)
Profit before taxes	531,166	419,385
Income taxes	(156,737)	(116,390)
Net income	374,429	302,995
Attributable to:		
Chugai shareholders	374,429	302,995
Earnings per share		
Basic (yen)	227.64	184.29
Diluted (yen)	227.57	184.17

2) Consolidated statement of comprehensive income in millions of yen

	Year ended December 31	
	2022	2021
Net income recognized in income statement	374,429	302,995
Other comprehensive income		
Remeasurements of defined benefit plans	3,021	583
Financial assets measured at fair value through OCI	(282)	(291)
Items that will never be reclassified to the income statement	2,739	292
Financial assets measured at fair value through OCI	(13)	3
Cash flow hedges	(8,759)	(292)
Currency translation of foreign operations	5,540	3,022
Items that are or may be reclassified to the income statement	(3,233)	2,733
Other comprehensive income, net of tax	(494)	3,025
Total comprehensive income	373,935	306,020
Attributable to:		
Chugai shareholders	373,935	306,020

(2) Consolidated balance sheet in millions of yen

	December 31, 2022	December 31, 2021
Assets		
Non-current assets:		
Property, plant and equipment	375,340	338,841
Right-of-use assets	11,311	13,266
Intangible assets	25,141	21,974
Financial non-current assets	1,837	2,393
Deferred tax assets	65,244	56,287
Defined benefit plan assets	5,172	1,327
Other non-current assets	49,176	40,944
Total non-current assets	533,221	475,033
Current assets:		
Inventories	292,206	208,838
Accounts receivable	512,538	355,081
Current income tax assets	1,745	928
Marketable securities	280,938	204,217
Cash and cash equivalents	222,169	267,753
Other current assets	26,941	26,844
Total current assets	1,336,537	1,063,661
Total assets	1,869,758	1,538,694
Liabilities		
Non-current liabilities:		
Deferred tax liabilities	(7,086)	(7,614)
Defined benefit plan liabilities	(3,311)	(2,945)
Long-term provisions	(2,756)	(2,101)
Other non-current liabilities	(8,489)	(10,595)
Total non-current liabilities	(21,641)	(23,255)
Current liabilities:		
Current income tax liabilities	(98,543)	(86,312)
Short-term provisions	(1,980)	(2,695)
Accounts payable	(209,835)	(152,266)
Other current liabilities	(113,372)	(86,149)
Total current liabilities	(423,730)	(327,422)
Total liabilities	(445,372)	(350,677)
Total net assets	1,424,387	1,188,017
Equity:		
Capital and reserves attributable to Chugai shareholders	1,424,387	1,188,017
Total equity	1,424,387	1,188,017
Total liabilities and equity	1,869,758	1,538,694

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

	Year ended December 31	
	2022	2021
Cash flows from operating activities		
Cash generated from operations	575,875	470,367
(Increase) decrease in working capital	(183,311)	(83,122)
Payments made for defined benefit plans	(3,739)	(3,665)
Utilization of provisions	(1,634)	(656)
Other operating cash flows	9,004	776
Cash flows from operating activities, before income taxes paid	396,194	383,700
Income taxes paid	(152,082)	(104,074)
Total cash flows from operating activities	244,112	279,626
Cash flows from investing activities		
Purchase of property, plant and equipment	(62,625)	(65,969)
Purchase of intangible assets	(8,614)	(6,897)
Disposal of property, plant and equipment	1,048	1,042
Interest and dividends received	281	133
Purchases of marketable securities	(518,681)	(362,761)
Sales of marketable securities	442,768	325,000
Purchases of investment securities	(321)	(9,503)
Sales of investment securities	151	28
Total cash flows from investing activities	(145,994)	(118,927)
Cash flows from financing activities		
Interest paid	(58)	(48)
Lease liabilities paid	(7,599)	(9,031)
Dividends paid to Chugai shareholders	(138,220)	(98,644)
Exercise of equity compensation plans	241	322
(Increase) decrease in own equity instruments	(5)	(8)
Total cash flows from financing activities	(145,641)	(107,408)
Net effect of currency translation on cash and cash equivalents	1,939	2,128
Increase (decrease) in cash and cash equivalents	(45,584)	55,419
Cash and cash equivalents at January 1	267,753	212,333
Cash and cash equivalents at December 31	222,169	267,753

(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, 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
Year ended December 31, 2022						
At January 1, 2022	73,202	68,223	1,054,050	(7,457)	1,188,017	1,188,017
Net income	—	—	374,429	—	374,429	374,429
Financial assets measured at fair value through OCI	—	—	—	(296)	(296)	(296)
Cash flow hedges	—	—	—	(8,759)	(8,759)	(8,759)
Currency translation of foreign operations	—	—	—	5,540	5,540	5,540
Remeasurements of defined benefit plans	—	—	3,021	—	3,021	3,021
Total comprehensive income	—	—	377,450	(3,515)	373,935	373,935
Dividends	—	—	(138,148)	—	(138,148)	(138,148)
Equity compensation plans	—	(379)	—	—	(379)	(379)
Own equity instruments	—	961	—	—	961	961
Transfer from other reserves to retained earnings	—	—	0	(0)	—	—
At December 31, 2022	73,202	68,806	1,293,352	(10,973)	1,424,387	1,424,387

(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 Board of Directors on February 2, 2023.

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% (61.13% 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, including that there is no material impact from the situation in Ukraine and the depreciation of yen.

However, should the situation persist, it could result in such risks as major revisions of the carrying amounts of assets and liabilities in the following fiscal year and beyond.

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, 2023 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

	2022			2021		
	Sales	Royalties and other operating income	Other revenue	Sales	Royalties and other operating income	Other revenue
Japan	654,663	2,610	—	518,948	3,449	—
Overseas	384,584	126,173	91,915	283,888	193,473	—
of which Switzerland	358,128	124,608	—	261,734	188,483	—
Total	1,039,247	128,784	91,915	802,836	196,922	—

Information by major customer in millions of yen

	2022	2021
F. Hoffmann-La Roche Ltd.	482,737	450,217
Ministry of Health, Labour and Welfare	203,655	77,449
Alfresa Corporation	91,655	104,690

3) Other expense

Chugai filed the Advance Pricing Arrangement covering certain transactions with F. Hoffmann-La Roche Ltd., to Japanese and Swiss tax authorities and received a notice of agreement. During the current fiscal year, Chugai received a revised 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 of the fiscal years 2017 and 2018 during the period in question.

As a result of this agreement, Chugai transferred a part of the deducted amount of income taxes to Roche as the estimated tax payable for Roche, in accordance with the license agreement between Chugai and Roche. In addition, it has posted ¥2,134 million of adjustment from transfer pricing taxation.

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

	2022	2021
Net income attributable to Chugai shareholders (millions of yen)	374,429	302,995
Weighted average number of common stock	1,679,057,667	1,679,057,667
Weighted average number of treasury stock	(34,259,939)	(34,907,198)
Weighted average number of shares in issue	1,644,797,728	1,644,150,469
Basic earnings per share (yen)	227.64	184.29

Diluted earnings per share

	2022	2021
Net income attributable to Chugai shareholders (millions of yen)	374,429	302,995
Weighted average number of shares in issue	1,644,797,728	1,644,150,469
Adjustment for assumed exercise of equity compensation plans, where dilutive	540,204	1,078,764
Weighted average number of shares in issue used to calculate diluted earnings per share	1,645,337,932	1,645,229,233
Diluted earnings per share (yen)	227.57	184.17

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

	2022	2021
Net income	374,429	302,995
Financing costs	61	48
Other financial income (expense)	(52)	(76)
Other expense	2,134	2,540
Income taxes	156,737	116,390
Operating profit	533,309	421,897
Depreciation of property, plant and equipment	23,690	20,974
Depreciation of right-of-use assets	4,717	5,890
Amortization of intangible assets	3,027	4,004
Impairment of property, plant and equipment	8	—
Impairment of intangible assets	633	6,342
Operating expense for defined benefit plans	4,721	4,316
Operating expense for equity-settled equity compensation plans	344	322
Net (income) expense for provisions	1,627	2,589
Inventory write-downs	2,482	1,350
Other adjustments	1,317	2,683
Cash generated from operations	575,875	470,367

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

	2022	2021
Interest received	278	131
Dividends received	3	3
Total	281	133

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 (2021: 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 in transactions 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, Roche has the pre-emptive right to acquire the shares, in order to maintain its current and future shareholding ratio in Chugai.

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 the 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 ¥84,476 million (2021: ¥60,340 million).

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

	2022	2021
Revenues	482,737	450,217
Purchases	398,245	219,314

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

	December 31, 2022	December 31, 2021
Accounts receivable	194,485	172,112
Trade accounts payable	121,185	81,648

c. Remuneration of key management personnel**Remuneration to the members of Board of Directors and Audit & Supervisory board** in millions of yen

	2022	2021
Board of Directors		
– Regular remuneration	243	274
– Bonuses	140	169
– Tenure-based restricted stock compensation	65	78
– Performance-based restricted stock compensation	68	94
Total	516	615
Audit & Supervisory Board		
– Regular remuneration	101	99
Total	101	99

7) Subsequent events

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