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CHUGAI PHARMACEUTICAL CO., LTD.

A member of the Roche group

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

Name of Company: Chugai Pharmaceutical Co., Ltd. October 24, 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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 Date of Submission of Quarterly Marketable Securities Filings: October 25, 2022
 Date on which Dividend Payments to Commence: —
 Supplementary Materials Prepared for the Quarterly Financial Statements: Yes
 Presentation Held to Explain the Quarterly 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 the third quarter of FY 2022 (January 1, 2022–September 30, 2022)

(1) Consolidated operating results

	Revenues	% change	Operating profit	% change	Net income	% change
First nine months of FY 2022	¥821,450 million	21.2	¥383,835 million	35.7	¥271,950 million	33.2
First nine months of FY 2021	¥677,493 million	17.5	¥282,835 million	24.4	¥204,154 million	25.7

	Net income attributable to Chugai shareholders	% change	Total comprehensive income	% change
First nine months of FY 2022	¥271,950 million	33.2	¥258,250 million	23.7
First nine months of FY 2021	¥204,154 million	25.7	¥208,791 million	28.8

	Earnings per share (Basic)	Earnings per share (Diluted)
First nine months of FY 2022	¥165.35	¥165.29
First nine months of FY 2021	¥124.17	¥124.09

Note: Percentages represent changes compared with the same period 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
As of Sep. 30, 2022	¥1,700,818 million	¥1,308,626 million	¥1,308,626 million	76.9%
As of Dec. 31, 2021	¥1,538,694 million	¥1,188,017 million	¥1,188,017 million	77.2%

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 ending Dec. 2022	—	¥38.00	—		
FY ending Dec. 2022 (Forecast)				¥38.00	¥76.00

Note: Whether the most recent dividend forecast has been revised: No

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

	Core revenues	% change	Core operating profit	% change	Core net income	% change
First nine months of FY 2022 (Results)	¥729,535 million	+63.4	¥299,033 million	+68.0	¥213,042 million	+68.2
FY ending Dec. 2022 (Forecast)	¥1,150,000 million	+15.0	¥440,000 million	+1.4	¥312,500 million	+0.3

	Core earnings per share	% change	Core dividend payout ratio %
First nine months of FY 2022 (Results)	¥129.48	+68.1	—
FY ending Dec. 2022 (Forecast)	¥190.00	+0.3	40.0

Notes: 1. Except for Core dividend payout ratio, percentages represent changes compared with the same period of the previous fiscal year for the forecasts, and the percentage of forecast levels that have been achieved to date for the results.

2. Whether the most recent forecasts for consolidated figures have been revised: No

3. 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)
- (b) Number of treasury stock at the end of the period
- (c) Average number of shares issued during the period (nine months)

As of Sep. 30, 2022	1,679,057,667	As of Dec. 31, 2021	1,679,057,667
As of Sep. 30, 2022	34,043,970	As of Dec. 31, 2021	34,739,943
First nine months of FY 2022	1,644,725,382	First nine months of FY 2021	1,644,108,077

Notes:

The quarterly financial statements are not subject to quarterly reviews.

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.

(3) For the specifics of the forecasts, please refer to "Consolidated Forecasts and Other forward-looking Statements" on page 7 of the attachment.

(4) Chugai is scheduled to hold a presentation of the financial statements 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 presentation.

Presentation for institutional investors, securities analysts and the media (Online conference) (Japanese only): October 24, 2022, Monday (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. Qualitative Information

(1) Consolidated operating results in billions of yen

	First nine months of FY 2022.12 (Jan. 1, 2022–Sep. 30, 2022)	First nine months of FY 2021.12 (Jan. 1, 2021–Sep. 30, 2021)	% change
Core results			
Revenues	729.5	677.5	+7.7
Sales	644.7	538.7	+19.7
Royalties and other operating income	84.9	138.8	(38.8)
Cost of sales	(262.4)	(225.7)	+16.3
Gross profit	467.1	451.8	+3.4
Marketing and distribution	(53.9)	(52.2)	+3.3
Research and development	(101.0)	(94.1)	+7.3
General and administration	(13.2)	(14.7)	(10.2)
Operating profit	299.0	290.7	+2.9
Net income	213.0	209.7	+1.6
IFRS results			
Revenues	821.5	677.5	+21.3
Operating profit	383.8	282.8	+35.7
Net income	272.0	204.2	+33.2

Consolidated financial highlights (IFRS results)

Revenues for the nine months under review were ¥821.5 billion (an increase of 21.3% year on year), operating profit for the nine months under review was ¥383.8 billion (an increase of 35.7% year on year), and net income for the nine months under review was ¥272.0 billion (an increase of 33.2% year on year). These results include non-Core items, such as amortization of intangible assets of ¥1.1 billion, impairment loss of intangible assets of ¥0.3 billion, and restructuring expenses etc. of ¥4.5 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 nine months under review were ¥729.5 billion (an increase of 7.7% year on year), due to a significant increase in sales, despite a decrease in royalties and other operating income.

Of revenues, sales were ¥644.7 billion (an increase of 19.7% 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 Kadcyła, and the supply of Ronapreve to the government, while sales were affected by the NHI drug price revisions of April 2021 and 2022 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 ¥84.9 billion (a decrease of 38.8% year on year), due to a significant decrease in royalty income from initial shipments of Hemlibra. Furthermore, cost to sales ratio was 40.7%, a 1.2 percentage point improvement year on year, reflecting a change in the product mix and other factors. As a result, gross profit amounted to ¥467.1 billion (an increase of 3.4% year on year).

Operating expenses were ¥168.1 billion (an increase of 4.3% year on year). Marketing and distribution expenses were ¥53.9 billion (an increase of 3.3% year on year) due to the effects of foreign exchange and other factors. Research and development expenses amounted to ¥101.0 billion (an increase of 7.3% year on year) due to an increase in expenses associated with the progress of projects, the effects of foreign exchange and other factors. General and administration expenses amounted to ¥13.2 billion (a decrease of 10.2% 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 ¥299.0 billion (an increase of 2.9% year on year) and net income was ¥213.0 billion (an increase of 1.6% year on year).

With regard to the effects of the changing situation in Russia and Ukraine on operating performance for the nine months 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 on page 1, entitled "Reconciliation of IFRS results to Core results."

Sales breakdown in billions of yen

	First nine months of FY 2022.12 (Jan. 1, 2022–Sep. 30, 2022)	First nine months of FY 2021.12 (Jan. 1, 2021–Sep. 30, 2021)	% change
Sales	644.7	538.7	+19.7
Domestic sales	387.6	362.6	+6.9
Oncology	186.5	191.1	(2.4)
Specialty*	201.0	171.6	+17.1
Overseas sales	257.1	176.0	+46.1

Domestic sales

Domestic sales were ¥387.6 billion (an increase of 6.9% year on year) due to the mainstay products and the favorable market penetration of the new products, while sales were significantly affected by the NHI drug price revisions of April 2021 and 2022 and the market penetration of generic drugs.

Oncology products sales were ¥186.5 billion (a decrease of 2.4% 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 Kadcyra (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 ¥201.0 billion (an increase of 17.1% year on year). Despite a sales decline of products including Ediro (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 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.

* "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 ¥257.1 billion (an increase of 46.1% year on year), far exceeding that of the previous fiscal year. The export of Hemlibra to Roche significantly increased to ¥132.9 billion (an increase of 121.5% 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 in December 2021 to treat patients with severe COVID-19, were favorable, increasing to ¥77.0 billion (an increase of 25.2% year on year). Furthermore, sales of Edirof launched in China in July 2022 were below ¥0.1 billion.

R&D activities

R&D expenses on a Core basis for the first nine months under review totaled ¥101.0 billion (an increase of 7.3% year on year), and the ratio of R&D expenses to revenues was 13.8%.

Progress made in R&D activities during the period from January 1, 2022 to September 30, 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) in consideration of the results of global Phase III study IMagyn050.
- 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.
- 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 domestic Phase II study for a RET inhibitor RG6396 for the treatment of NSCLC (2nd Line) in June 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 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 decided to discontinue the development of an anti-TIGIT human monoclonal antibody RG6058 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 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. 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 bispecific antibody DONQ52 for the treatment of celiac disease in September 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 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: Ediol) 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.

(2) Consolidated financial position**Assets, liabilities and net assets** in billions of yen

	September 30, 2022	December 31, 2021	Change in amount
Net operating assets (NOA) and Net assets			
Net working capital	366.2	370.1	(3.9)
Long-term net operating assets	432.8	402.4	30.4
Net operating assets (NOA)	799.0	772.6	26.4
Net cash	545.3	472.0	73.3
Other non-operating assets – net	(35.6)	(56.5)	20.9
Total net assets	1,308.6	1,188.0	120.6
Consolidated balance sheet (IFRS basis)			
Total assets	1,700.8	1,538.7	162.1
Total liabilities	(392.2)	(350.7)	(41.5)
Total net assets	1,308.6	1,188.0	120.6

Net operating assets (NOA) at September 30, 2022 were ¥799.0 billion, an increase of ¥26.4 billion since the end of the previous fiscal year. Of NOA, net working capital was ¥366.2 billion, a decrease of ¥3.9 billion from the end of the previous fiscal year, due mainly to a decrease in accounts receivable, in spite of an increase in inventories and the payment for the manufacturing building for active pharmaceutical ingredients (APIs) (FJ3) in the Fujieda Plant. Long-term net operating assets increased by ¥30.4 billion to ¥432.8 billion since the end of the previous fiscal year, mainly due to the investments in the Chugai Life Science Park Yokohama, the new manufacturing building for APIs (FJ2) in the Fujieda Plant, and the manufacturing building for APIs of biopharmaceuticals (UK4) in the Ukima Site.

As indicated in “Cash flows” on the next page, net cash, including marketable securities and interest-bearing debt, increased by ¥73.3 billion since the end of the previous fiscal year to ¥545.3 billion. Other non-operating assets – net increased by ¥20.9 billion since the end of the previous fiscal year to ¥(35.6) billion due mainly to a decrease in current income tax liabilities.

As a consequence, total net assets were ¥1,308.6 billion (an increase of ¥120.6 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.

Cash flows in billions of yen

	First nine months of FY 2022.12 (Jan. 1, 2022–Sep. 30, 2022)	First nine months of FY 2021.12 (Jan. 1, 2021–Sep. 30, 2021)	% change
Free cash flows			
Operating profit - IFRS basis	383.8	282.8	+35.7
Operating profit, net of operating cash adjustments	410.3	312.6	+31.3
Operating free cash flows	361.0	219.8	+64.2
Free cash flows	207.3	114.3	+81.4
Net change in net cash	73.3	18.0	+307.2
Consolidated statement of cash flows (IFRS basis)			
Cash flows from operating activities	271.1	184.7	+46.8
Cash flows from investing activities	(124.0)	(101.8)	+21.8
Cash flows from financing activities	(143.3)	(104.4)	+37.3
Net change in cash and cash equivalents	6.2	(19.8)	–
Cash and cash equivalents at September 30	274.0	192.5	+42.3

Operating profit, net of operating cash adjustments, amounted to ¥410.3 billion (an increase of 31.3% 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 nine months under review was a net inflow of ¥361.0 billion (an increase of 64.2% year on year) mainly due to an increase in operating profit and a decrease in net working capital, etc. of ¥15.5 billion, despite expenditures of ¥50.7 billion for the purchase of property, plant and equipment. Factors accounting for the decrease in net working capital, etc. are as indicated in “Assets, liabilities and net assets” on the previous page.

Free cash flows were a net cash inflow of ¥207.3 billion (an increase of 81.4% year on year) due mainly to income taxes paid of ¥151.1 billion from operating free cash flows.

The net change in net cash calculated by adjusting for dividends paid of ¥137.8 billion, etc. from free cash flows was an increase of ¥73.3 billion.

The net change in cash and cash equivalents, excluding changes in marketable securities and interest-bearing debt, was a net cash inflow of ¥6.2 billion. The cash and cash equivalents balance at the end of this period amounted to ¥274.0 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.”

(3) Consolidated forecasts and other forward-looking statements

Chugai has not made any changes in its forecast of consolidated results for the fiscal year ending December 31, 2022 since the announcement regarding the forecast issued on February 3, 2022.

Note: In “1. Qualitative Information,” 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. Interim Condensed Consolidated Financial Statements and Major Notes

(1) Interim condensed consolidated income statement and interim condensed consolidated statement of comprehensive income

1) Interim condensed consolidated income statement in millions of yen

	First nine months ended September 30	
	2022	2021
Revenues	821,450	677,493
Sales	644,673	538,694
Royalties and other operating income	84,862	138,799
Other revenue	91,915	—
Cost of sales	(263,343)	(227,591)
Gross profit	558,107	449,902
Marketing and distribution	(54,112)	(52,246)
Research and development	(104,394)	(99,492)
General and administration	(15,767)	(15,329)
Operating profit	383,835	282,835
Financing costs	(45)	(36)
Other financial income (expense)	562	945
Other expense	(2,401)	(2,799)
Profit before taxes	381,950	280,945
Income taxes	(110,000)	(76,791)
Net income	271,950	204,154
Attributable to:		
Chugai shareholders	271,950	204,154
Earnings per share		
Basic (yen)	165.35	124.17
Diluted (yen)	165.29	124.09

2) Interim condensed consolidated statement of comprehensive income in millions of yen

	First nine months ended September 30	
	2022	2021
Net income recognized in income statement	271,950	204,154
Other comprehensive income		
Financial assets measured at fair value through OCI	(293)	(110)
Items that will never be reclassified to the income statement	(293)	(110)
Financial assets measured at fair value through OCI	(10)	6
Cash flow hedges	(20,030)	2,544
Currency translation of foreign operations	6,632	2,197
Items that are or may be reclassified to the income statement	(13,407)	4,747
Other comprehensive income, net of tax	(13,700)	4,637
Total comprehensive income	258,250	208,791
Attributable to:		
Chugai shareholders	258,250	208,791

(2) Interim condensed consolidated balance sheet in millions of yen

	September 30, 2022	December 31, 2021
Assets		
Non-current assets:		
Property, plant and equipment	361,144	338,841
Right-of-use assets	12,073	13,266
Intangible assets	26,335	21,974
Financial non-current assets	1,822	2,393
Deferred tax assets	68,229	56,287
Defined benefit plan assets	324	1,327
Other non-current assets	46,324	40,944
Total non-current assets	516,251	475,033
Current assets:		
Inventories	313,015	208,838
Accounts receivable	274,658	355,081
Current income tax assets	766	928
Marketable securities	271,252	204,217
Cash and cash equivalents	274,043	267,753
Other current assets	50,833	26,844
Total current assets	1,184,567	1,063,661
Total assets	1,700,818	1,538,694
Liabilities		
Non-current liabilities:		
Deferred tax liabilities	(6,809)	(7,614)
Defined benefit plan liabilities	(3,638)	(2,945)
Long-term provisions	(3,413)	(2,101)
Other non-current liabilities	(9,366)	(10,595)
Total non-current liabilities	(23,226)	(23,255)
Current liabilities:		
Current income tax liabilities	(48,796)	(86,312)
Short-term provisions	(1,271)	(2,695)
Accounts payable	(188,216)	(152,266)
Other current liabilities	(130,683)	(86,149)
Total current liabilities	(368,966)	(327,422)
Total liabilities	(392,192)	(350,677)
Total net assets	1,308,626	1,188,017
Equity:		
Capital and reserves attributable to Chugai shareholders	1,308,626	1,188,017
Total equity	1,308,626	1,188,017
Total liabilities and equity	1,700,818	1,538,694

(3) Interim condensed consolidated statement of cash flows in millions of yen

	First nine months ended September 30	
	2022	2021
Cash flows from operating activities		
Cash generated from operations	414,162	315,280
(Increase) decrease in working capital	15,548	(21,488)
Payments made for defined benefit plans	(1,849)	(1,900)
Utilization of provisions	(1,335)	(375)
Other operating cash flows	(4,321)	(3,250)
Cash flows from operating activities, before income taxes paid	422,205	288,266
Income taxes paid	(151,090)	(103,597)
Total cash flows from operating activities	271,115	184,669
Cash flows from investing activities		
Purchase of property, plant and equipment	(50,662)	(58,139)
Purchase of intangible assets	(8,570)	(6,876)
Disposal of property, plant and equipment	1,131	1,079
Interest and dividends received	195	100
Purchases of marketable securities	(393,685)	(277,764)
Sales of marketable securities	327,768	240,000
Purchases of investment securities	(307)	(161)
Sales of investment securities	151	—
Total cash flows from investing activities	(123,979)	(101,760)
Cash flows from financing activities		
Interest paid	(44)	(36)
Lease liabilities paid	(5,671)	(6,327)
Dividends paid to Chugai shareholders	(137,798)	(98,324)
Exercise of equity compensation plans	229	266
(Increase) decrease in own equity instruments	(4)	(7)
Total cash flows from financing activities	(143,286)	(104,428)
Net effect of currency translation on cash and cash equivalents	2,441	1,703
Increase (decrease) in cash and cash equivalents	6,291	(19,816)
Cash and cash equivalents at January 1	267,753	212,333
Cash and cash equivalents at September 30	274,043	192,518

(4) Interim condensed consolidated statement of changes in equity in millions of yen**For the first nine months ended September 30, 2021 (Jan. 1, 2021–Sep. 30, 2021)**

	Attributable to Chugai shareholders					Total equity
	Share capital	Capital surplus	Retained earnings	Other reserves	Subtotal	
At January 1, 2021	73,202	67,586	849,093	(9,879)	980,003	980,003
Net income	—	—	204,154	—	204,154	204,154
Financial assets measured at fair value through OCI	—	—	—	(105)	(105)	(105)
Cash flow hedges	—	—	—	2,544	2,544	2,544
Currency translation of foreign operations	—	—	—	2,197	2,197	2,197
Total comprehensive income	—	—	204,154	4,637	208,791	208,791
Dividends	—	—	(98,642)	—	(98,642)	(98,642)
Equity compensation plans	—	(87)	—	—	(87)	(87)
Own equity instruments	—	584	—	—	584	584
At September 30, 2021	73,202	68,084	954,605	(5,242)	1,090,649	1,090,649

For the first nine months ended September 30, 2022 (Jan. 1, 2022–Sep. 30, 2022)

	Attributable to Chugai shareholders					Total equity
	Share capital	Capital surplus	Retained earnings	Other reserves	Subtotal	
At January 1, 2022	73,202	68,223	1,054,050	(7,457)	1,188,017	1,188,017
Net income	—	—	271,950	—	271,950	271,950
Financial assets measured at fair value through OCI	—	—	—	(303)	(303)	(303)
Cash flow hedges	—	—	—	(20,030)	(20,030)	(20,030)
Currency translation of foreign operations	—	—	—	6,632	6,632	6,632
Total comprehensive income	—	—	271,950	(13,700)	258,250	258,250
Dividends	—	—	(138,148)	—	(138,148)	(138,148)
Equity compensation plans	—	(427)	—	—	(427)	(427)
Own equity instruments	—	934	—	—	934	934
Transfer from other reserves to retained earnings	—	—	0	(0)	—	—
At September 30, 2022	73,202	68,730	1,187,852	(21,158)	1,308,626	1,308,626

(5) Notes regarding the going concern assumption

None

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

These financial statements are the interim condensed consolidated financial statements (“Interim 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 Interim Financial Statements were approved by the Board of Directors on October 24, 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 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 Quarterly Consolidated Financial Statements” (Japanese Cabinet Ordinance No. 64, 2007). Hence, in accordance with Article 93 of the same Ordinance, the Interim Financial Statements have been prepared in accordance with International Accounting Standard (IAS) No. 34 “Interim Financial Reporting.”

The Interim Financial Statements should be used with the consolidated financial statements for the year ended December 31, 2021 as they do not include all the information as required for the consolidated financial statements for the full fiscal year.

The Interim 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 Interim 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 Interim 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 significant accounting policies that were used for the Consolidated Financial Statements in the previous fiscal year to the Interim Financial Statements.