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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 2021)

Name of Company: Chugai Pharmaceutical Co., Ltd. October 22, 2021
 Stock Listing: Tokyo Stock Exchange
 Security Code No.: 4519 (URL <https://www.chugai-pharm.co.jp/english>)
 Representative: Osamu Okuda, President & CEO
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 Phone: +81-(0)3-3273-0554
 Date of Submission of Quarterly Marketable Securities Filings: October 27, 2021
 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 2021 (January 1, 2021–September 30, 2021)

(1) Consolidated operating results

	Revenues	% change	Operating profit	% change	Net income	% change
First nine months of FY 2021	¥677,493 million	17.5	¥282,835 million	24.4	¥204,154 million	25.7
First nine months of FY 2020	¥576,520 million	13.3	¥227,318 million	41.3	¥162,425 million	38.4

	Net income attributable to Chugai shareholders	% change	Total comprehensive income	% change
First nine months of FY 2021	¥204,154 million	25.7	¥208,791 million	28.8
First nine months of FY 2020	¥162,425 million	38.4	¥162,150 million	41.5

	Earnings per share (Basic)	Earnings per share (Diluted)
First nine months of FY 2021	¥124.17	¥124.09
First nine months of FY 2020	¥98.84	¥98.74

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

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

(2) Consolidated results (balance sheet)

	Total assets	Total equity	Equity attributable to Chugai shareholders	Ratio of equity attributable to Chugai shareholders
As of Sep. 30, 2021	¥1,353,363 million	¥1,090,649 million	¥1,090,649 million	80.6%
As of Dec. 31, 2020	¥1,235,498 million	¥980,003 million	¥980,003 million	79.3%

2. Dividends

	Annual dividends per share				
	End of first quarter	End of second quarter	End of third quarter	End of fiscal year	Total
FY ended Dec. 2020	—	¥75.00	—	¥30.00	—
FY ending Dec. 2021	—	¥30.00	—		

Notes: 1. Whether the most recent dividend forecast has been revised: Yes

2. The dividend forecast for the fiscal year ending December 31, 2021 is not determined at this time.

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

Reference: Regarding the revised dividend forecast, please refer to “Notice of Revisions to Dividend Forecast for Fiscal Year Ending December 31, 2021” announced today October 22, 2021 and “Consolidated Forecasts and Other forward-looking Statements” on page 7 of the attachment.

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

	Revenues	% change	Core operating profit	% change	Core net income	% change
First nine months of FY 2021 (Results)	¥677,493 million	+69.8	¥290,748 million	+72.7	¥209,677 million	+71.6
FY ending Dec. 2021 (Revised forecast)	¥970,000 million	+23.3	¥400,000 million	+29.9	¥293,000 million	+33.5
FY ending Dec. 2021 (Original forecast)	¥800,000 million	+1.7	¥320,000 million	+3.9	¥232,000 million	+5.7

	Core earnings per share		Core dividend payout ratio %
First nine months of FY 2021 (Results)	¥127.45	+71.6	—
FY ending Dec. 2021 (Revised forecast)	¥178.00	+33.4	Undecided
FY ending Dec. 2021 (Original forecast)	¥141.00	+5.7	42.6

Notes: 1. Percentages shown for forecasts of revenues, Core operating profit, Core net income and Core EPS represent changes compared with the same period of the previous fiscal year. Percentages for results represent the percentage of revised forecast levels that have been achieved to date.

2. Whether the most recent forecasts for consolidated figures have been revised: Yes

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.

Reference: Regarding the revised consolidated forecasts please refer to “Notice of Revisions to Financial Forecasts” announced today October 22, 2021 and “Consolidated Forecasts and Other forward-looking Statements” on page 7 of the attachment.

4. Others

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

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

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

As of Sep. 30, 2021	1,679,057,667	As of Dec. 31, 2020	1,679,057,667
As of Sep. 30, 2021	34,797,562	As of Dec. 31, 2020	35,186,586
First nine months of FY 2021	1,644,108,077	First nine months of FY 2020	1,643,316,680

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

(c) Average number of shares issued during the period (nine months)

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

Notes:

The 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 tele-conference 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.

Tele-conference for institutional investors, securities analysts and the media (Japanese only): October 22, 2021, Friday (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 2021.12 (Jan. 1, 2021–Sep. 30, 2021)	First nine months of FY 2020.12 (Jan. 1, 2020–Sep. 30, 2020)	% change
Core results			
Revenues	677.5	576.5	+17.5
Sales	538.7	464.8	+15.9
Royalties and other operating income	138.8	111.7	+24.3
Cost of sales	(225.7)	(200.3)	+12.7
Gross profit	451.8	376.2	+20.1
Marketing and distribution	(52.2)	(49.0)	+6.5
Research and development	(94.1)	(82.2)	+14.5
General and administration	(14.7)	(13.1)	+12.2
Operating profit	290.7	231.9	+25.4
Net income	209.7	165.6	+26.6
IFRS results			
Revenues	677.5	576.5	+17.5
Operating profit	282.8	227.3	+24.4
Net income	204.2	162.4	+25.7

Consolidated financial highlights (IFRS results)

Revenues for the nine months under review were ¥677.5 billion (an increase of 17.5% year on year), operating profit for the nine months under review was ¥282.8 billion (an increase of 24.4% year on year), and net income for the nine months under review was ¥204.2 billion (an increase of 25.7% year on year). These results include non-Core items, such as amortization of intangible assets of ¥1.9 billion, impairment loss of intangible assets of ¥2.7 billion, and restructuring expenses etc. of ¥3.3 billion, 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 ¥677.5 billion (an increase of 17.5% year on year), due to a significant increase in sales, royalties and other operating income.

Of revenues, sales were ¥538.7 billion (an increase of 15.9% year on year). Within domestic sales the sales grew significantly over the previous fiscal year due to the steady market penetration of the mainstay products, Tecentrig and new products Polivy and Enspryng, 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 compared to the previous fiscal year since the exports of Hemlibra and Alecensa to Roche increased while the export of Actemra decreased significantly. Royalties and other operating income amounted to ¥138.8 billion (an increase of 24.3% year on year), mainly due to an increase in royalties related to Hemlibra and its profit-sharing income, despite a decrease in other operating income resulting from one-time income. Furthermore, cost to sales ratio was 41.9%, a 1.2 percentage point improvement year on year. As a result, gross profit amounted to ¥451.8 billion (an increase of 20.1% year on year).

Operating expenses were ¥161.1 billion (an increase of 11.6% year on year). Marketing and distribution expenses were ¥52.2 billion (an increase of 6.5% year on year) while the expenses had been significantly affected by the decrease in activities during COVID-19 pandemic last year. Research and development expenses amounted to ¥94.1 billion (an increase of 14.5% year on year) due to an increase in expenses associated with the progress of projects, etc. General and administration expenses amounted to ¥14.7 billion (an increase of 12.2% year on year) primarily due to increases in the enterprise tax (pro forma standard taxation) and various expenses. As a result, Core operating profit was ¥290.7 billion (an increase of 25.4% year on year) and Core net income was ¥209.7 billion (an increase of 26.6% year on year).

Note: Core results

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

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

Sales breakdown in billions of yen

	First nine months of FY 2021.12 (Jan. 1, 2021–Sep. 30, 2021)	First nine months of FY 2020.12 (Jan. 1, 2020–Sep. 30, 2020)	% change
Sales	538.7	464.8	+15.9
Domestic sales	362.6	303.2	+19.6
Oncology	191.1	169.4	+12.8
Primary	171.6	133.8	+28.3
Overseas sales	176.0	161.6	+8.9

Domestic sales

Domestic sales were ¥362.6 billion (an increase of 19.6% year on year) due to the favorable market penetration of the mainstay products and new products, while sales were affected by the NHI drug price revisions of April 2020 and 2021 and the market penetration of generic drugs.

Oncology products sales were ¥191.1 billion (an increase of 12.8% year on year). Sales increased due to the favorable market penetration of Polivy (an antimicrotubule binding anti-CD79b monoclonal antibody, anti-cancer agent), which was launched in May of this year, in addition to the steady market penetration of the mainstay product, Tecentriq (an anti PD-L1 humanized monoclonal antibody, anti-cancer agent) and the favorable sales of Kadcyra (an anti-HER2 antibody-tubulin polymerization inhibitor conjugate), despite a sales decline of Herceptin (an anti-HER2 humanized monoclonal antibody, anti-cancer agent) and Rituxan (an anti-CD20 monoclonal antibody, anti-cancer agent) affected by the market penetration of generic drugs.

Primary products sales were ¥171.6 billion (an increase of 28.3% year on year). This was mainly due to posting sales from the supply of Ronapreve (anti-SARS-CoV-2 monoclonal antibody) to the government, which received the special approval for emergency in July of this year, in addition to the steady market penetration of Enspryng (a pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody), which was launched in August of last year and the favorable sales of the mainstay product, Hemlibra (blood coagulation factor VIII substitute) and Actemra (a humanized anti-human IL-6 receptor monoclonal antibody).

Overseas sales

Overseas sales amounted to ¥176.0 billion (an increase of 8.9% year on year). The export of Actemra to Roche significantly decreased compared to the previous fiscal year. This was due to an increase in export of Actemra, including those for clinical trials for COVID-19 pneumonia, in the same period of the previous fiscal year. Meanwhile, the exports of Hemlibra and Alecensa (an ALK inhibitor, anti-cancer agent) to Roche were favorable and significantly increased compared to the previous fiscal year.

R&D activities

R&D expenses on a Core basis for the first nine months under review totaled ¥94.1 billion (an increase of 14.5% year on year), and the ratio of R&D expenses to revenue was 13.9%.

Progress made in R&D activities during the period from January 1, 2021 to September 30, 2021 was as follows.

Oncology

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

Renal disease

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

Autoimmune Diseases

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

Neurology

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

Other Diseases

- We started Phase I study for SARS-CoV-2 neutralizing antibody cocktail RG6413/RG6412 (Product name: Ronapreve) for the treatment of COVID-19 in March and filed for the special approval for emergency in June, and obtained approval for the treatment of COVID-19 in July 2021.
- We filed anti-VEGF/Ang2 bispecific antibody RG7716 for the treatment of diabetic macular edema and neovascular age-related macular degeneration in June 2021. Also, we started global Phase III study for RG7716 for the treatment of retinal vein occlusion in March 2021.
- We started global Phase III study for RNA polymerase inhibitor RG6422 for the treatment of COVID-19 in April 2021.
- We started Phase I study for anti-FGFR1/KLB bispecific antibody RG7992 for the treatment of non-alcoholic steatohepatitis in June 2021.

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

	September 30, 2021	December 31, 2020	Change in amount
Net operating assets (NOA) and Net assets			
Net working capital	324.5	300.0	24.5
Long-term net operating assets	383.7	346.0	37.7
Net operating assets (NOA)	708.2	646.0	62.2
Net cash	396.6	378.6	18.0
Other non-operating assets – net	(14.2)	(44.6)	30.4
Total net assets	1,090.6	980.0	110.6
Consolidated balance sheet (IFRS basis)			
Total assets	1,353.4	1,235.5	117.9
Total liabilities	(262.7)	(255.5)	(7.2)
Total net assets	1,090.6	980.0	110.6

Net operating assets (NOA) at September 30, 2021 were ¥708.2 billion, an increase of ¥62.2 billion since the end of the previous fiscal year. Of NOA, net working capital was ¥324.5 billion (an increase of ¥24.5 billion since the end of the previous fiscal year), due mainly to an increase in accounts receivable. Long-term net operating assets increased by ¥37.7 billion to ¥383.7 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 “Cash flows” on the next page, net cash, including marketable securities and interest-bearing debt, increased by ¥18.0 billion since the end of the previous fiscal year to ¥396.6 billion. Other non-operating assets – net increased by ¥30.4 billion since the end of the previous fiscal year to ¥(14.2) billion due mainly to a decrease in current income tax liabilities.

As a consequence, total net assets were ¥1,090.6 billion (an increase of ¥110.6 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 2021.12 (Jan. 1, 2021–Sep. 30, 2021)	First nine months of FY 2020.12 (Jan. 1, 2020–Sep. 30, 2020)	% change
Free cash flows			
Operating profit - IFRS basis	282.8	227.3	+24.4
Operating profit, net of operating cash adjustments	312.6	253.0	+23.6
Operating free cash flows	219.8	140.3	+56.7
Free cash flows	114.3	76.4	+49.6
Net change in net cash	18.0	(14.3)	—
Consolidated statement of cash flows (IFRS basis)			
Cash flows from operating activities	184.7	132.8	+39.1
Cash flows from investing activities	(101.8)	(57.1)	+78.3
Cash flows from financing activities	(104.4)	(97.2)	+7.4
Net change in cash and cash equivalents	(19.8)	(21.2)	(6.6)
Cash and cash equivalents at September 30	192.5	182.7	+5.4

Operating profit, net of operating cash adjustments, amounted to ¥312.6 billion (an increase of 23.6% 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 ¥219.8 billion (an increase of 56.7% year on year) mainly due to an increase in operating profit despite an increase in net working capital, etc. of ¥21.5 billion, as well as expenditures, etc. of ¥58.1 billion for the purchase of property, plant and equipment. Factors accounting for the increase 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 ¥114.3 billion (an increase of 49.6% year on year) due mainly to income taxes paid of ¥103.6 billion.

The net change in net cash calculated by subtracting dividends paid of ¥98.3 billion, etc. from free cash flows was an increase of ¥18.0 billion.

The net change in cash and cash equivalents, excluding changes in marketable securities and interest-bearing debt, was a net cash outflow of ¥19.8 billion. The cash and cash equivalents balance at the end of this period amounted to ¥192.5 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**(a) Consolidated forecasts for FY 2021 (January 1, 2021–December 31, 2021)**

The full-year consolidated forecasts have been revised from the original forecasts announced on Feb 4, 2021.

	Revenues	Core operating profit	Core earnings per share	Core dividend payout ratio %
FY ending Dec. 2021 Original forecast (A)	¥800.0 billion	¥320.0 billion	¥141.00	42.6
FY ending Dec. 2021 Revised forecast (B)	¥970.0 billion	¥400.0 billion	¥178.00	Undecided
Change (B-A)	+ ¥170.0 billion	+ ¥80.0 billion	+ ¥37.00	—
Change (%)	+21.3	+25.0	+26.2	—
FY ended Dec. 2020 (Results)	¥786.9 billion	¥307.9 billion	¥133.39	41.2

Revenues have been revised to ¥970.0 billion, an increase of ¥170.0 billion from the original forecast announced on Feb 4, 2021.

For domestic sales, forecasted sales amount attributable to the supply of Ronapreve to the government for the fiscal year has been included, and the progress and revised assumptions for each product including Avastin and Tecentriq, which have progressed better than the original forecast have been reflected. For overseas sales, exports of Actemra and Hemlibra to Roche have been forecasted to be higher than the original forecast. For royalties and other operating income, the forecast of income and one-time income for Actemra and Hemlibra has also been updated.

Core operating profit forecast has also been revised to ¥400.0 billion, an increase of ¥80.0 billion from the original forecast. In addition to the above-mentioned revision of revenue forecast, higher cost to sales ratio due to a change in the product mix from the original assumption, etc., foreign exchange effects and increases in some expenses attributable to increased sales and profits have been included.

Core EPS is forecasted to be ¥178.00, an increase of ¥37.00 from the original forecast.

Year-end dividend forecast and the forecast for the Core dividend payout ratio have not been determined at this time.

The revised full-year consolidated forecasts are based on updated foreign exchange rate assumptions: 1CHF = 117 JPY, 1EUR = 130 JPY, 1USD = 107 JPY, and 1SGD = 81 JPY.

(b) Revision of Dividend Forecast

Year-end dividend forecast has been revised to undecided as shown in the table below due to the business environment which has been changing significantly.

Year-end dividend will be decided after the fiscal year end based on basic profit distribution principles*.

*Regarding income distribution, taking into account changes in the strategic funding needs and earning prospects, Chugai aims for a consolidated dividend payout ratio of 45% on average in comparison with Core EPS to continue to provide a stable allocation of profit to all shareholders.

	Dividend per share		
	End of second quarter	End of fiscal year	Total
FY ending Dec. 2021 Original forecast (A)	¥30.00	¥30.00	¥60.00
FY ending Dec. 2021 Revised forecast (B)	—	Undecided	Undecided
FY ending Dec. 2021	¥30.00	—	—
FY ended Dec. 2020	¥75.00	¥30.00	—

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

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	
	2021	2020
Revenues	677,493	576,520
Sales	538,694	464,790
Royalties and other operating income	138,799	111,729
Cost of sales	(227,591)	(201,200)
Gross profit	449,902	375,320
Marketing and distribution	(52,246)	(49,785)
Research and development	(99,492)	(85,018)
General and administration	(15,329)	(13,199)
Operating profit	282,835	227,318
Financing costs	(36)	(42)
Other financial income (expense)	945	(991)
Other expense	(2,799)	(1,147)
Profit before taxes	280,945	225,138
Income taxes	(76,791)	(62,713)
Net income	204,154	162,425
Attributable to:		
Chugai shareholders	204,154	162,425
Earnings per share		
Basic (yen)	124.17	98.84
Diluted (yen)	124.09	98.74

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

	First nine months ended September 30	
	2021	2020
Net income recognized in income statement	204,154	162,425
Other comprehensive income		
Financial assets measured at fair value through OCI	(110)	148
Items that will never be reclassified to the income statement	(110)	148
Financial assets measured at fair value through OCI	6	7
Cash flow hedges	2,544	(748)
Currency translation of foreign operations	2,197	317
Items that are or may be reclassified to the income statement	4,747	(423)
Other comprehensive income, net of tax	4,637	(275)
Total comprehensive income	208,791	162,150
Attributable to:		
Chugai shareholders	208,791	162,150

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

	September 30, 2021	December 31, 2020
Assets		
Non-current assets:		
Property, plant and equipment	327,598	289,218
Right-of-use assets	5,599	8,272
Intangible assets	24,792	23,880
Financial non-current assets	2,683	2,841
Deferred tax assets	50,370	47,934
Defined benefit plan assets	—	492
Other non-current assets	28,727	27,954
Total non-current assets	439,769	400,592
Current assets:		
Inventories	201,421	183,893
Accounts receivable	292,443	253,342
Current income tax assets	913	12
Marketable securities	204,131	166,287
Cash and cash equivalents	192,518	212,333
Other current assets	22,168	19,039
Total current assets	913,595	834,906
Total assets	1,353,363	1,235,498
Liabilities		
Non-current liabilities:		
Deferred tax liabilities	(7,888)	(9,166)
Defined benefit plan liabilities	(3,257)	(2,282)
Long-term provisions	(1,907)	(2,142)
Other non-current liabilities	(4,993)	(5,835)
Total non-current liabilities	(18,046)	(19,425)
Current liabilities:		
Current income tax liabilities	(42,043)	(63,171)
Short-term provisions	(432)	(358)
Accounts payable	(138,262)	(100,396)
Other current liabilities	(63,932)	(72,146)
Total current liabilities	(244,669)	(236,070)
Total liabilities	(262,714)	(255,495)
Total net assets	1,090,649	980,003
Equity:		
Capital and reserves attributable to Chugai shareholders	1,090,649	980,003
Total equity	1,090,649	980,003
Total liabilities and equity	1,353,363	1,235,498

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

	First nine months ended September 30	
	2021	2020
Cash flows from operating activities		
Cash generated from operations	315,280	256,601
(Increase) decrease in working capital	(21,488)	(56,051)
Payments made for defined benefit plans	(1,900)	(1,758)
Utilization of provisions	(375)	—
Other operating cash flows	(3,250)	391
Cash flows from operating activities, before income taxes paid	288,266	199,183
Income taxes paid	(103,597)	(66,369)
Total cash flows from operating activities	184,669	132,814
Cash flows from investing activities		
Purchase of property, plant and equipment	(58,139)	(47,301)
Purchase of intangible assets	(6,876)	(3,079)
Disposal of property, plant and equipment	1,079	(25)
Interest and dividends received	100	72
Purchases of marketable securities	(277,764)	(182,996)
Sales of marketable securities	240,000	176,000
Purchases of investment securities	(161)	(70)
Sales of investment securities	—	326
Total cash flows from investing activities	(101,760)	(57,072)
Cash flows from financing activities		
Interest paid	(36)	(22)
Lease liabilities paid	(6,327)	(6,285)
Dividends paid to Chugai shareholders	(98,324)	(91,227)
Exercise of equity compensation plans	266	386
(Increase) decrease in own equity instruments	(7)	(28)
Total cash flows from financing activities	(104,428)	(97,176)
Net effect of currency translation on cash and cash equivalents	1,703	205
Increase (decrease) in cash and cash equivalents	(19,816)	(21,229)
Cash and cash equivalents at January 1	212,333	203,941
Cash and cash equivalents at September 30	192,518	182,711

(4) Interim condensed consolidated statement of changes in equity in millions of yen**For the first nine months ended September 30, 2020 (Jan. 1, 2020–Sep. 30, 2020)**

	Attributable to Chugai shareholders					Total equity
	Share capital	Capital surplus	Retained earnings	Other reserves	Subtotal	
At January 1, 2020	73,016	67,037	722,076	(8,143)	853,985	853,985
Net income	—	—	162,425	—	162,425	162,425
Financial assets measured at fair value through OCI	—	—	—	155	155	155
Cash flow hedges	—	—	—	(748)	(748)	(748)
Currency translation of foreign operations	—	—	—	317	317	317
Total comprehensive income	—	—	162,425	(275)	162,150	162,150
Dividends	—	—	(91,467)	—	(91,467)	(91,467)
Equity compensation plans	186	(798)	—	—	(613)	(613)
Own equity instruments	—	1,214	—	—	1,214	1,214
Transfer from other reserves to retained earnings	—	—	106	(106)	—	—
At September 30, 2020	73,202	67,453	793,140	(8,524)	925,270	925,270

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

(5) Notes regarding the going concern assumption

None

(6) Notes regarding the interim condensed 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 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 22, 2021.

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% (61.16% of the total number of shares issued excluding treasury stock). The Group became principal members of the Roche Group after entering into a strategic alliance in October 2002.

The Group meets all of the requirements for a “Specified Company under Designated International Financial Reporting Standards” as stipulated under Article 1-2 of the “Ordinance on Terminology, Forms, and Preparation Methods of 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, 2020 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 without any significant effects including the effects of COVID-19. However, there is a possibility that the epidemic situation of COVID-19 becomes a significant risk that will cause material corrections to the carrying amounts of assets and liabilities in the next fiscal year and beyond due to the uncertainties of the future changes.

c. Significant accounting policies

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

2) Subsequent events

Chugai decided to construct a new manufacturing building for biopharmaceutical active pharmaceutical ingredients (APIs) (UK4) for early-stage investigational drugs on October 22, 2021.

a. Purpose of the construction

Chugai has been actively investing in manufacturing facilities in anticipation of the consecutive launch of innovative biopharmaceuticals using its antibody engineering technologies. Besides existing API manufacturing buildings for biopharmaceuticals (UK1 and UK2), Chugai constructed a new manufacturing building (UK3) for late-stage investigational drugs and initial commercial products, which started to operate in 2018. The addition of UK4, which specializes in the production of investigational drugs for early clinical trials, will reinforce Chugai's streamlined manufacturing capability, from investigational drugs for early clinical development to initial commercial products. This will provide a more robust foundation to support the development and launch of innovative drug candidates.

b. Details of the assets

Location: 5-5-1 Ukima, Kita-ku, Tokyo (In the Ukima Branch)

Total Investment: 12.1 billion yen

c. Construction timetable

Date of approval by the Board of Directors: October 22, 2021

Start of Construction: February, 2022

Completion of Construction: April, 2023

Completion of Building: September, 2023

Start of Operation: January, 2024