



Kyowa Kirin Co., Ltd.

Consolidated Financial Summary (IFRS) Fiscal 2021

(January 1, 2021 – December 31, 2021)

This document is an English translation of parts of the Japanese-language original.

SUMMARY OF CONSOLIDATED FINANCIAL STATEMENTS (IFRS)
for Fiscal Year Ended December 31, 2021

(The twelve-month period from January 1, 2021 to December 31, 2021)

February 7, 2022

Company Name: Kyowa Kirin Co., Ltd.

Listed Exchanges: 1st Section of the Tokyo Stock Exchange

Stock Code: 4151

President & Chief Executive Officer: Masashi Miyamoto

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Scheduled date of Ordinary General Meeting of Shareholders: March 25, 2022

Scheduled start date of dividend payment: March 28, 2022

Scheduled date of submission of Annual Securities Report: March 8, 2022

Appendix materials to accompany the annual financial report: Yes

FY2021 earnings presentation meeting: Yes (for institutional investors and securities analysts)

(Millions of yen rounded off)

1. Consolidated Financial Results for the Fiscal Year Ended December 31, 2021
(from January 1, 2021 to December 31, 2021)

(1) Consolidated operating results

(Percentages indicate year-on-year changes.)

| | Revenue | | Core operating profit | | Profit before tax | | Profit | |
|-------------------|-----------------|------|-----------------------|-----|-------------------|------|-----------------|--------|
| | Millions of yen | % | Millions of yen | % | Millions of yen | % | Millions of yen | % |
| Fiscal year ended | | | | | | | | |
| December 31, 2021 | 352,246 | 10.6 | 65,685 | 9.6 | 60,050 | 14.9 | 52,347 | 11.3 |
| December 31, 2020 | 318,352 | 4.1 | 59,955 | 1.0 | 52,263 | 17.5 | 47,027 | (29.9) |

Total comprehensive income: Fiscal year ended December 31, 2021: ¥62,751 million; 43.9%

Fiscal year ended December 31, 2020: ¥43,611 million; (40.4)%

Note: Core operating profit was calculated by deducting "selling, general and administrative expenses" and "research and development expenses" from "gross profit," and adding "share of profit (loss) of investments accounted for using equity method" to the amount.

| | Profit attributable to owners of parent | | Basic earnings per share | Diluted earnings per share | Return on equity attributable to owners of parent | Profit before tax to total assets ratio |
|-------------------|---|--------|--------------------------|----------------------------|---|---|
| | Millions of yen | % | Yen | Yen | % | % |
| Fiscal year ended | | | | | | |
| December 31, 2021 | 52,347 | 11.3 | 97.43 | 97.39 | 7.3 | 7.0 |
| December 31, 2020 | 47,027 | (29.9) | 87.56 | 87.50 | 6.8 | 6.6 |

(Reference) Share of profit (loss) of investments accounted for using equity method:

Fiscal year ended December 31, 2021: ¥4,575 million;

Fiscal year ended December 31, 2020: ¥964 million

(2) Consolidated financial position

| | Total assets | Total equity | Equity attributable to owners of parent | Ratio of equity attributable to owners of parent to total assets | Equity attributable to owners of parent per share |
|-------------------|-----------------|-----------------|---|--|---|
| | Millions of yen | Millions of yen | Millions of yen | % | Yen |
| As of | | | | | |
| December 31, 2021 | 921,872 | 737,162 | 737,162 | 80.0 | 1,371.90 |
| December 31, 2020 | 801,290 | 698,396 | 698,396 | 87.2 | 1,300.12 |

(3) Consolidated cash flows

| | Net cash provided by (used in) operating activities | Net cash provided by (used in) investing activities | Net cash provided by (used in) financing activities | Cash and cash equivalents at end of period |
|-------------------|---|---|---|--|
| Fiscal year ended | Millions of yen | Millions of yen | Millions of yen | Millions of yen |
| December 31, 2021 | 86,548 | (11,363) | (28,446) | 335,084 |
| December 31, 2020 | 39,502 | 252,559 | (26,003) | 287,019 |

2. Dividends

| | Dividends per share | | | | | Total dividend amount | Dividend payout ratio (consolidated) | Ratio of dividends to equity attributable to owners of parent (consolidated) |
|---|--------------------------|---------------------------|--------------------------|--------------------|-------|-----------------------------|--|--|
| | First quarter- end | Second quarter- end | Third quarter- end | Fiscal year-end | Total | | | |
| | Yen | Yen | Yen | Yen | Yen | Millions of yen | % | % |
| Fiscal year ended December 31, 2020 | – | 22.00 | – | 22.00 | 44.00 | 23,636 | 50.3 | 3.4 |
| Fiscal year ended December 31, 2021 | – | 23.00 | – | 23.00 | 46.00 | 24,717 | 43.2 | 3.4 |
| Fiscal year ending December 31, 2022 (Forecast) | – | 24.00 | – | 24.00 | 48.00 | | 47.9 | |

Note: The figure of “dividend payout ratio (consolidated)” for the fiscal year ended December 31, 2020 indicates the dividend payout ratio based on basic earnings per share, and the figures for the fiscal year ended December 31, 2021 and the fiscal year ending December 31, 2022 (forecast) indicate the dividend payout ratio based on core EPS (calculated as an indicator showing recurring profitability by dividing core profit (determined by subtracting “other income,” “other expenses” and the related “income tax expense” from “profit”) by the average number of shares during the period).

3. Consolidated Earnings Forecasts for the Fiscal Year Ending December 31, 2022
(from January 1, 2022 to December 31, 2022)

(Percentages indicate year-on-year changes.)

| | Revenue | | Core operating profit | | Profit before tax | | Profit | | Profit attributable to owners of parent | | Basic earnings per share |
|-----------|--------------------|-----|--------------------------|-----|--------------------|-----|--------------------|-----|--|-----|--------------------------------|
| | Millions of yen | % | Millions of yen | % | Millions of yen | % | Millions of yen | % | Millions of yen | % | Yen |
| Full year | 380,000 | 7.9 | 67,000 | 2.0 | 66,000 | 9.9 | 53,000 | 1.2 | 53,000 | 1.2 | 98.64 |

*** Notes**

(1) Changes to significant subsidiaries during the period (Changes of specified subsidiaries resulting in changes in the scope of consolidation during the period under review): No

(2) Changes in accounting policies, and accounting estimates:

a. Changes in accounting policies required by IFRS: No

b. Changes in accounting policies other than a. above: No

c. Changes in accounting estimates: No

(3) Number of shares issued (ordinary shares)

a. Number of shares issued (including treasury shares)

| | |
|-------------------------|--------------------|
| As of December 31, 2021 | 540,000,000 shares |
| As of December 31, 2020 | 540,000,000 shares |

b. Number of treasury shares

| | |
|-------------------------|------------------|
| As of December 31, 2021 | 2,671,817 shares |
| As of December 31, 2020 | 2,823,975 shares |

c. Average number of shares during the period

| | |
|----------------------------|--------------------|
| FY ended December 31, 2021 | 537,272,070 shares |
| FY ended December 31, 2020 | 537,109,444 shares |

(Reference)

Non-Consolidated Results for the Fiscal Year Ended December 31, 2021 (Japanese GAAP)
(from January 1, 2021 to December 31, 2021)

(1) Non-consolidated operating results

(Percentages indicate year-on-year changes.)

| Fiscal year ended | Net sales | | Operating profit | | Ordinary profit | | Profit | |
|-------------------|-----------------|-------|------------------|--------|-----------------|--------|-----------------|--------|
| | Millions of yen | % | Millions of yen | % | Millions of yen | % | Millions of yen | % |
| December 31, 2021 | 237,590 | (6.1) | 24,802 | (49.0) | 35,228 | (28.9) | 66,366 | 112.4 |
| December 31, 2020 | 252,933 | 2.7 | 48,669 | (2.7) | 49,562 | (32.4) | 31,250 | (65.8) |

| Fiscal year ended | Basic earnings per share | Diluted earnings per share |
|-------------------|--------------------------|----------------------------|
| | Yen | Yen |
| December 31, 2021 | 123.52 | 123.47 |
| December 31, 2020 | 58.18 | 58.15 |

(2) Non-consolidated financial position

| As of | Total assets | Net assets | Equity ratio | Net assets per share |
|-------------------|-----------------|-----------------|--------------|----------------------|
| | Millions of yen | Millions of yen | % | Yen |
| December 31, 2021 | 794,087 | 596,921 | 75.1 | 1,110.13 |
| December 31, 2020 | 687,680 | 555,730 | 80.7 | 1,033.43 |

(Reference) Equity: As of December 31, 2021: ¥596,507 million; As of December 31, 2020: ¥555,135 million

- * These financial results reports are exempt from audit conducted by certified public accountants or an audit corporation.

- * Notice regarding the appropriate use of the earnings forecasts and other special comments
The forward-looking statements, including earnings forecasts, contained in these materials are based on the information currently available to the Company and on certain assumptions deemed to be reasonable by management. As such, they do not constitute guarantees by the Company of future performance. Actual results may differ materially from these projections for a wide variety of reasons. For more information regarding our suppositions that form the assumptions for the earnings forecasts, please see pages 17 and 18 of the attachment, “(5) Outlook for Fiscal 2022” in “1. Summary of Business Performance and Financial Position.”

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1. Summary of Business Performance and Financial Position

< Overview of business >

Responding to the massive changes to the business and social environments occurring as a result of the global spread of the novel coronavirus disease (COVID-19) since 2020, the Kyowa Kirin Group (the “Group”) has been striving to provide stable supply of pharmaceuticals, which is a core mission of a pharmaceutical company, as an utmost priority, and while paying meticulous attention to preventing infection, carrying out activities such as maintaining production and logistics and collecting and providing information. In tandem with those efforts, the Group proceeded with initiatives for the initial year of the FY2021-2025 Medium Term Business Plan aimed at realizing the Group’s new vision: Kyowa Kirin will realize the successful creation and delivery of life-changing value that ultimately makes people smile, as a Japan-based Global Specialty Pharmaceutical company built on the diverse team of experts with shared passion for innovation.

While faced with addressing the changes in the healthcare environment and restrictions on business activities worldwide due to COVID-19 continuing on from 2020, the Group continued to achieve steady growth from global strategic products such as Crysvida[®] and POTELIGEO[®]. Among the next-generation strategic products, the Group has decided to make KHK4083, which is steadily advancing in development for indications in the therapeutic areas of immunology/allergy, available to more patients as soon as possible by forming a collaboration with Amgen Inc. of the United States, which has already shown steady results in these areas. In addition, the Group is making steady progress in its collaboration with MEI Pharma of the United States to jointly develop ME-401 (generic name: Zandelisib) in the therapeutic area of oncology.

Meanwhile, the Group was not able to obtain approval in Europe for the global strategic product Istradefylline (product name in Japan: NOURIAST[®]), a treatment for Parkinson’s Disease. The Group will continue to closely watch the judgments of the authorities of each country and region in the future for items pending applications and approval. In addition, we will respond appropriately to issues regarding stable supply structures through implementing both in-house and contracted manufacturing. Regarding initiatives aimed at both realizing a sustainable society and achieving business growth, the Group continued to engage in awareness raising activities on illnesses as part of the response to patient-centered healthcare needs, and in November 2021, the Group declared its support for the recommendations of the Task Force on Climate-Related Financial Disclosures (TCFD) in response to global climate change.

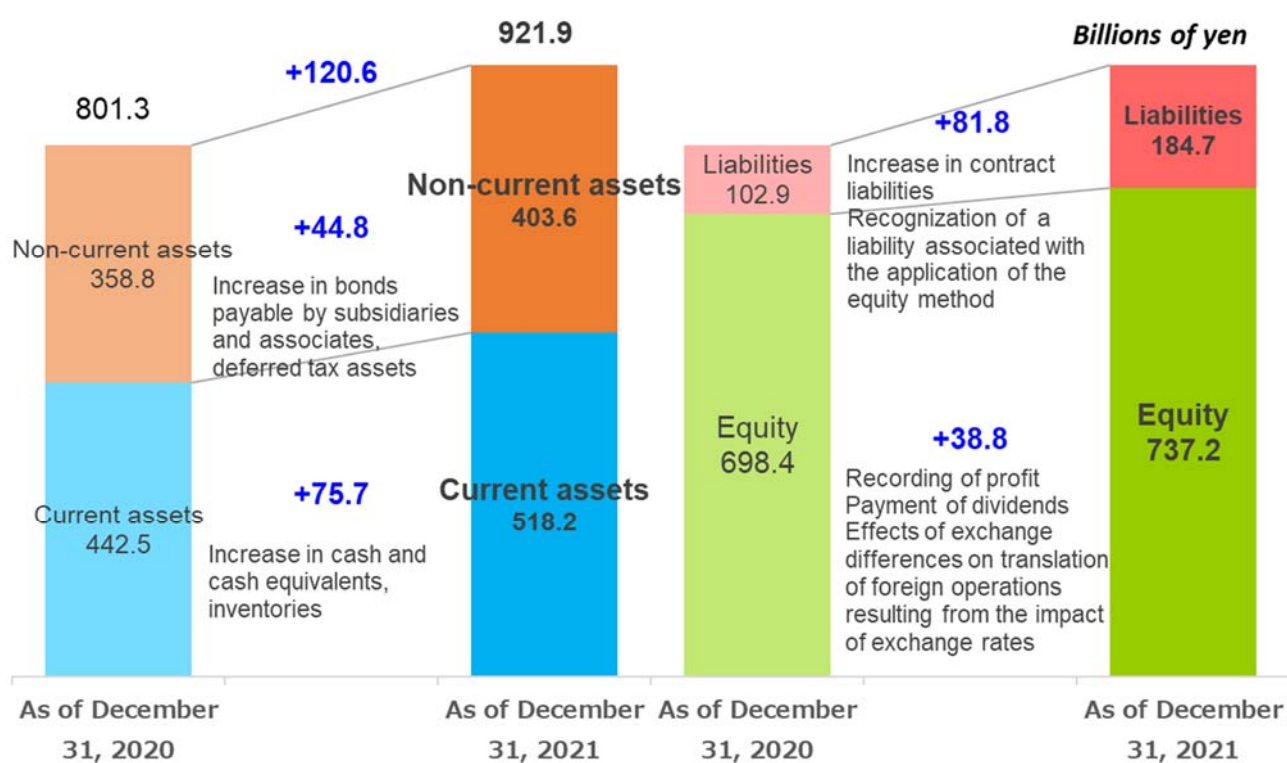
(1) Summary of Consolidated Financial Position for Fiscal 2021

(Billions of yen)

| | As of December 31, 2020 | As of December 31, 2021 | Year-on-year change |
|--|----------------------------|----------------------------|---------------------|
| Assets | 801.3 | 921.9 | 120.6 |
| Non-current assets | 358.8 | 403.6 | 44.8 |
| Current assets | 442.5 | 518.2 | 75.7 |
| Liabilities | 102.9 | 184.7 | 81.8 |
| Equity | 698.4 | 737.2 | 38.8 |
| Ratio of equity attributable to owners of parent to total assets (%) | 87.2% | 80.0% | (7.2)% |

- Assets as of December 31, 2021, were ¥921.9 billion, an increase of ¥120.6 billion compared to the end of the previous fiscal year.
- Non-current assets increased by ¥44.8 billion compared to the end of the previous fiscal year, to ¥403.6 billion, with downward pressure from factors such as the impairment of marketing rights and the sale of investment securities being more than offset by positive changes, which included an

- increase in bonds payable by subsidiaries and associates following a shift away from accounting for bonds of FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. using the equity method, and a rise in deferred tax assets.
- Current assets increased by ¥75.7 billion to ¥518.2 billion, due mainly to an increase in cash and cash equivalents from the proceeds from sale of assets held for sale (shares of Hitachi Chemical Diagnostics Systems Co., Ltd.) and proceeds from upfront payment received from Amgen Inc. based on an agreement for joint development and commercialization of KHK4083, as well as an increase in inventories, despite a decrease in assets held for sale.
 - Liabilities as of December 31, 2021, were ¥184.7 billion, an increase of ¥81.8 billion compared to the end of the previous fiscal year, due mainly to an increase in contract liabilities accompanying the conclusion of an agreement with Amgen Inc., and the recording of liabilities from application of equity method for FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd. following a shift away from accounting for bonds payable by subsidiaries and associates using the equity method.
 - Equity as of December 31, 2021, was ¥737.2 billion, an increase of ¥38.8 billion compared to the end of the previous fiscal year, due mainly to an increase due to the recording of profit attributable to owners of parent as well as an increase in exchange differences on translation of foreign operations resulting from the impact of exchange rates, despite a decrease due to the payment of dividends, etc. As a result, the ratio of equity attributable to owners of parent to total assets was 80.0%, a decrease of 7.2 percentage points compared to the end of the previous fiscal year.



(2) Summary of Business Performance in Fiscal 2021

1) Overview of results

The Group now applies the International Financial Reporting Standards (“IFRS”) in line with its policy of expanding business globally, and adopts “core operating profit” as a level of profit that shows the recurring profitability from operating activities. Core operating profit is calculated by deducting “selling, general and administrative expenses” and “research and development expenses” from “gross profit,” and adding “share of profit (loss) of investments accounted for using equity method” to the amount.

(Billions of yen)

| | Fiscal year ended December 31, 2020 | Fiscal year ended December 31, 2021 | Year-on-year change | Rate of change (%) |
|---|-------------------------------------|-------------------------------------|---------------------|--------------------|
| Revenue | 318.4 | 352.2 | 33.9 | 10.6% |
| Core operating profit | 60.0 | 65.7 | 5.7 | 9.6% |
| Profit before tax | 52.3 | 60.1 | 7.8 | 14.9% |
| Profit attributable to owners of parent | 47.0 | 52.3 | 5.3 | 11.3% |

< Average exchange rates for each period >

| Currency | Fiscal year ended December 31, 2020 | Fiscal year ended December 31, 2021 | Year-on-year change |
|-------------|-------------------------------------|-------------------------------------|---------------------|
| USD (USD/¥) | ¥107 | ¥109 | Up ¥2 |
| GBP (GBP/¥) | ¥137 | ¥150 | Up ¥13 |
| CNY (CNY/¥) | ¥15.5 | ¥16.9 | Up ¥1.4 |

For the fiscal year ended December 31, 2021, revenue was ¥352.2 billion (up 10.6% compared to the previous fiscal year) and core operating profit was ¥65.7 billion (up 9.6%). Profit attributable to owners of parent was ¥52.3 billion (up 11.3%).

- The increase in revenue was the result of steady growth of global strategic products in North America and EMEA, despite lower revenue in Japan. The positive effect on revenue from foreign exchange was ¥9.0 billion.
- Core operating profit rose, despite increases in selling, general and administrative expenses and research and development expenses, due to higher gross profit resulting from an increase in overseas revenue, as well as a rise in the share of profit of investments accounted for using equity method. The positive effect on core operating profit from foreign exchange was ¥2.5 billion.
- Profit attributable to owners of parent increased as a result of a decrease in other expenses in addition to an increase in core operating profit, despite an increase in income tax expense.

2) Revenue by regional control function

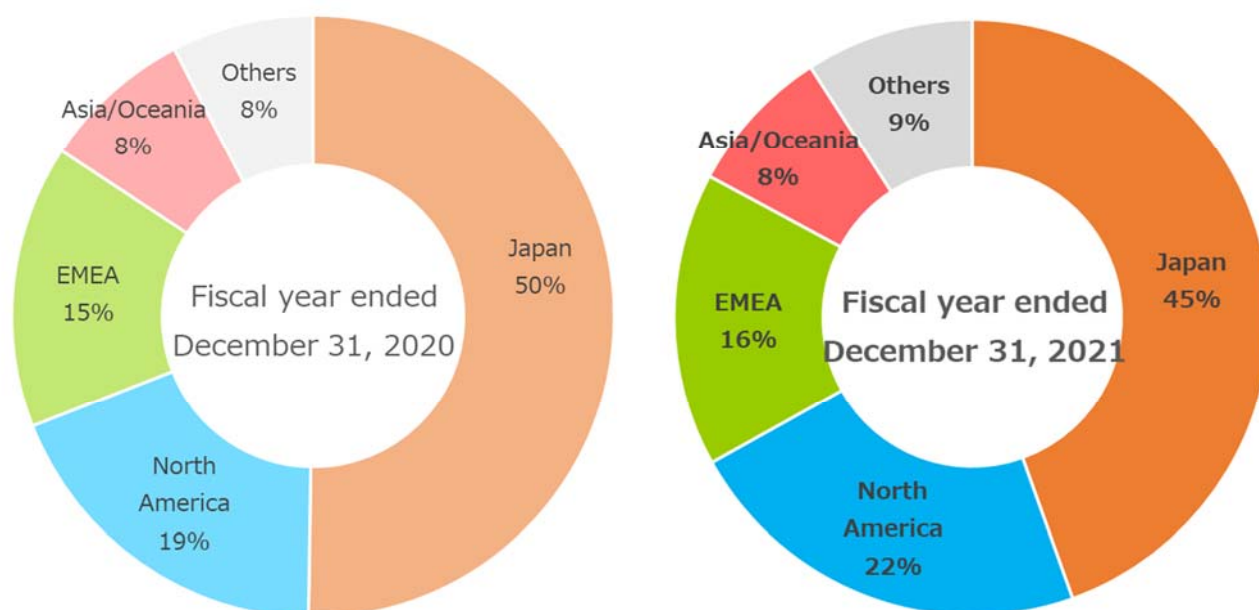
(Billions of yen)

| | Fiscal year ended December 31, 2020 | Fiscal year ended December 31, 2021 | Year-on-year change | Rate of change (%) |
|----------------------------|-------------------------------------|-------------------------------------|---------------------|--------------------|
| Japan | 159.9 | 156.9 | (3.1) | (1.9)% |
| North America | 59.9 | 78.8 | 18.9 | 31.4% |
| EMEA | 48.4 | 56.1 | 7.7 | 16.0% |
| Asia/Oceania | 25.9 | 28.4 | 2.5 | 9.6% |
| Others | 24.2 | 32.1 | 7.9 | 32.6% |
| Total consolidated revenue | 318.4 | 352.2 | 33.9 | 10.6% |

Notes: 1. Revenue by regional control function is classified based on consolidated revenue from products of regional control functions in the One Kyowa Kirin structure (a global management structure with axes combining four regions – Japan, North America, EMEA, and Asia/Oceania – and the functions needed by a global specialty pharmaceutical company).

2. EMEA consists of Europe, the Middle East, Africa, etc.
3. Others consists of revenue from technology out-licensing, original equipment manufacturing, etc.

Composition of revenue by regional control function



< Revenue of major products (Japan) >

(Billions of yen)

| | Fiscal year ended December 31, 2020 | Fiscal year ended December 31, 2021 | Year-on-year change | Rate of change (%) |
|--|-------------------------------------|-------------------------------------|---------------------|--------------------|
| Darbepoetin Alfa Injection Syringe [KKF] | 25.2 | 22.3 | (2.9) | (11.4)% |
| G-Lasta | 26.7 | 29.4 | 2.7 | 10.0% |
| Nourias | 9.4 | 8.7 | (0.7) | (7.5)% |
| Crysvita | 3.8 | 7.2 | 3.4 | 89.7% |
| (Reference) Asacol, Minirinmelt and Desmopressin | 1.9 | – | (1.9) | (100.0)% |

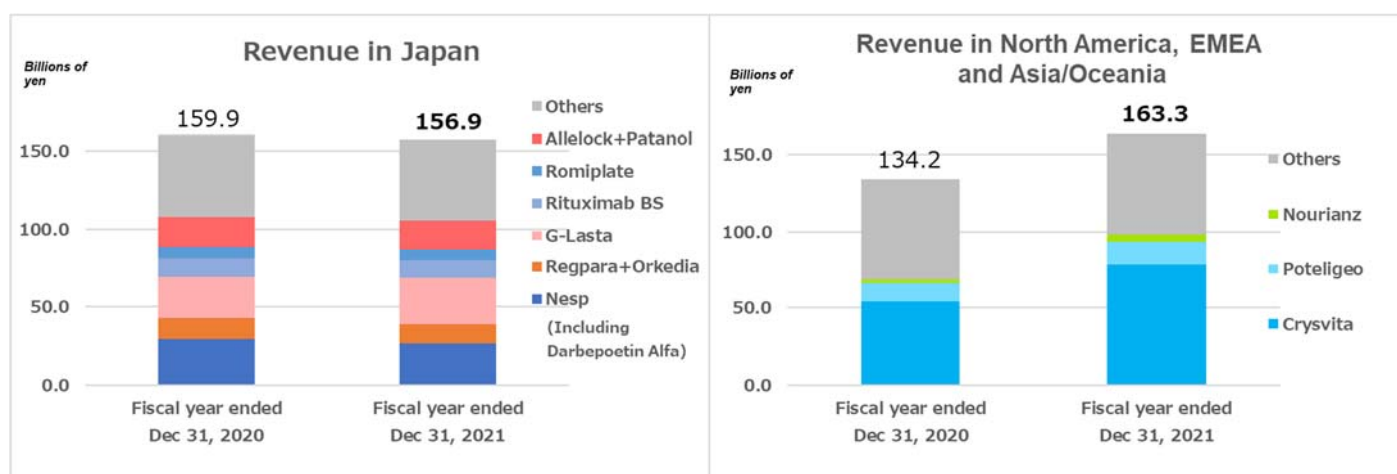
- Revenue in Japan decreased year on year due to the impact of the expiration of co-marketing agreements for some products, in addition to the impact of the reductions in drug price standards implemented in April 2020 and April 2021, despite the growth in sales of new product groups, such as Crysvita[®], a treatment for FGF23-related diseases.
 - Revenue from Darbepoetin Alfa Injection Syringe [KKF], a renal anemia treatment drug, decreased due to the impact of the market penetration of rival products.
 - Firm growth in revenue was realized for G-Lasta[®], an agent for decreasing the incidence of febrile neutropenia.
 - Revenue from NOURIAST[®], an antiparkinsonian agent, decreased due to the impact of the market penetration of rival products.
 - Crysvita[®], a treatment for FGF23-related diseases, has been penetrating the market favorably since their launch in 2019.
 - Revenue from ASACOL[®], an ulcerative colitis treatment drug, and MINIRINMELT[®] and DESMOPRESSIN, which are treatments for central diabetes insipidus, decreased as a result of the Company discontinuing its sales of ASACOL[®] on March 31, 2020 and MINIRINMELT[®] and DESMOPRESSIN on April 27, 2020.

< Revenue of major products (overseas) >

(Billions of yen)

| | Fiscal year ended December 31, 2020 | Fiscal year ended December 31, 2021 | Year-on-year change | Rate of change (%) |
|-----------|-------------------------------------|-------------------------------------|---------------------|--------------------|
| Crysvita | 54.4 | 78.3 | 23.9 | 44.0% |
| Poteligeo | 11.5 | 15.3 | 3.7 | 32.5% |
| Nourianz | 2.6 | 4.5 | 1.9 | 74.1% |
| Abstral | 10.2 | 8.5 | (1.6) | (16.1)% |
| Regpara | 8.3 | 7.4 | (0.9) | (11.1)% |

- Revenue in North America increased year on year due to the steady growth of global strategic products.
 - Revenue from Crysvita[®], a treatment for X-linked hypophosphatemia, has been growing steadily since its launch in 2018. Approval for additional indication for treatment of tumor induced osteomalacia was acquired in June 2020.
 - Firm growth in revenue was realized for POTELIGEO[®], an anticancer agent.
 - Revenue from NOURIANZ[™] (product name in Japan: NOURIAST[®]), an antiparkinsonian agent, has been growing since its launch in October 2019.
- Revenue in EMEA increased year on year due to the steady growth of global strategic products.
 - Revenue from Crysvita[®], a treatment for X-linked hypophosphatemia, has been growing steadily as the number of countries where it has been released has been increasing since its launch in 2018. Approval for sale with the extended indication for older adolescents and adults was acquired in September 2020.
 - Sales of POTELIGEO[®], an anticancer agent, was launched in June 2020 in Germany, and it has been penetrating the market favorably as the number of countries where it has been released has been increasing.
 - Revenue from Abstral[®], a treatment for cancer pain, decreased year on year due mainly to the impact of the market penetration of generics and shipping schedule adjustments.
- Revenue in Asia/Oceania increased year on year.
 - Revenue from REGPARA[®], a treatment for secondary hyperparathyroidism, declined after it became subject to China's centralized governmental purchasing system in October 2021.



- Revenue from Others increased year on year due to an increase in revenue from technology out-licensing.
 - Technology out-licensing increased in conjunction with the conclusion of an agreement with Amgen Inc. to jointly develop and commercialize KHK4083, anti-OX40 fully human monoclonal antibody for the treatment of atopic dermatitis, with potential in other autoimmune diseases, and the conclusion of an agreement to grant Aevi Genomic Medicine, LLC the rights to develop, manufacture and commercialize the human anti-LIGHT monoclonal antibody for all indications worldwide, in addition to an increase in royalties revenue from AstraZeneca in relation to benralizumab.

3) Core operating profit

Billions of yen



- Core operating profit rose compared to the previous fiscal year due mainly to higher gross profit following an increase in overseas revenue mainly of global strategic products, and rise in the share of profit of investments accounted for using equity method. These factors more than offset increases in selling, general and administrative expenses and research and development expenses, which were aimed at maximizing the value of global strategic products and rapidly establishing competitive global business bases.

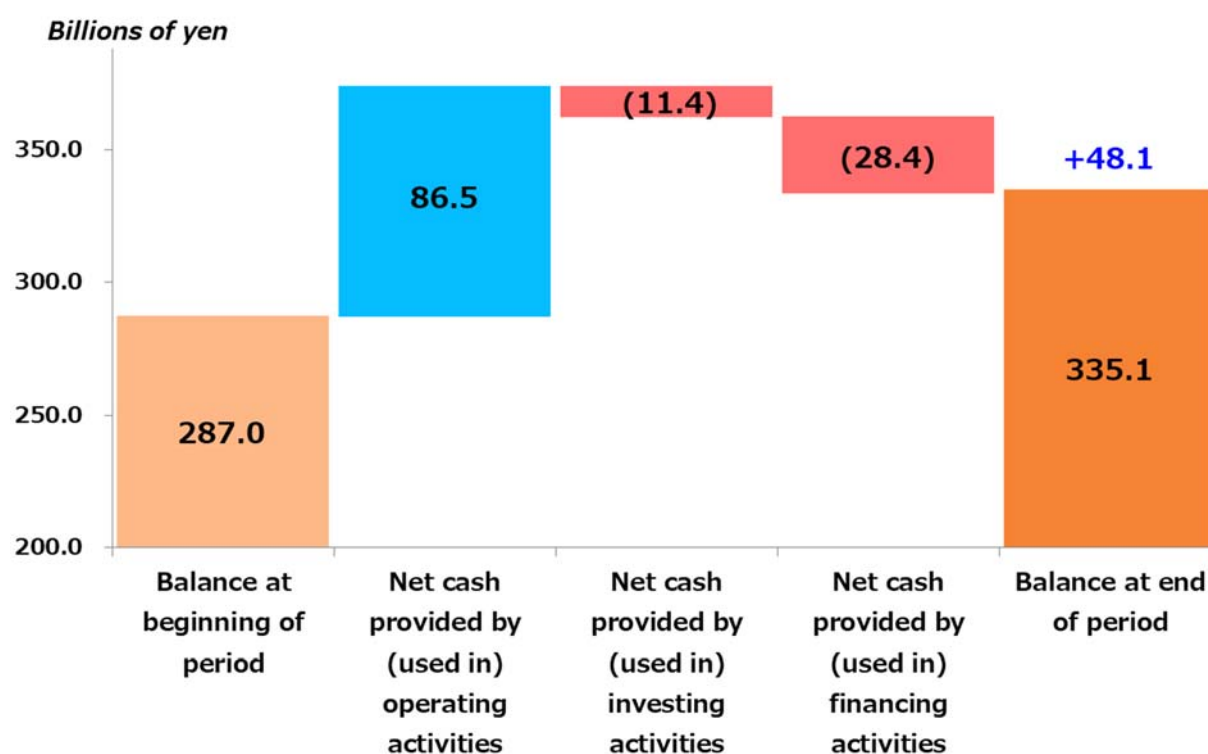
(3) Cash Flow Summary for Fiscal 2021*(Billions of yen)*

| | Fiscal year ended December 31, 2020 | Fiscal year ended December 31, 2021 | Year-on-year change | Year-on-year (%) |
|---|---|---|------------------------|---------------------|
| Net cash provided by (used in) operating activities | 39.5 | 86.5 | 47.0 | 119.1% |
| Net cash provided by (used in) investing activities | 252.6 | (11.4) | (263.9) | – |
| Net cash provided by (used in) financing activities | (26.0) | (28.4) | (2.4) | 9.4% |
| Cash and cash equivalents at beginning of period | 20.8 | 287.0 | 266.3 | – |
| Cash and cash equivalents at end of period | 287.0 | 335.1 | 48.1 | 16.7% |

- Cash and cash equivalents as of December 31, 2021, were ¥335.1 billion, an increase of ¥48.1 billion compared with the balance of ¥287.0 billion as of December 31, 2020.

The main contributing factors affecting cash flow during the current fiscal year were as follows:

- Net cash provided by operating activities was ¥86.5 billion, compared with net cash provided by operating activities of ¥39.5 billion in the previous fiscal year. Major inflows included increase (decrease) in contract liabilities of ¥38.8 billion, which included proceeds of USD400 million from upfront payment received from Amgen Inc. based on an agreement for joint development and commercialization of KHK4083, in addition to profit before tax of ¥60.1 billion and depreciation and amortization of ¥19.5 billion. Major outflows included income taxes paid of ¥14.8 billion.
- Net cash used in investing activities was ¥11.4 billion, compared with net cash provided by investing activities of ¥252.6 billion in the previous fiscal year. Major outflows included ¥13.2 billion for purchase of intangible assets and ¥6.5 billion for purchase of property, plant and equipment. Major inflows included proceeds from sale of investments accounted for using equity method of ¥5.1 billion, and proceeds from sale of investment securities of ¥1.9 billion.
- Net cash used in financing activities was ¥28.4 billion, compared with net cash used in financing activities of ¥26.0 billion in the previous fiscal year. Major outflows included dividends paid of ¥24.2 billion.



(4) Research and Development Activities

The Group continuously and actively invests resources in research and development activities. We aim to advance both a technological pillar that can build a platform for applying various modalities and discovering innovative drugs and a disease pillar that continues to provide “only-one value drugs” for diseases for which there are no effective treatments while utilizing the disease science accumulated by the Group thus far, build a highly competitive pipeline, and provide new drugs with life-changing value worldwide.

For the fiscal year ended December 31, 2021, the Group’s research and development expenses totaled ¥57.7 billion, and our progress in the respective disease fields of our main late-stage development products are as follows. (“◆” indicates the progress made during the fourth quarter of fiscal 2021.)

Nephrology

RTA 402

- In January 2021, we started a phase III clinical study in Japan for treatment of autosomal dominant polycystic kidney disease.
- In July 2021, we applied for approval for treatment of Alport Syndrome in Japan.

KHK7791

- In April 2021, we started a phase III clinical study in Japan for treatment of hyperphosphatemia in patients receiving hemodialysis and peritoneal dialysis.

Oncology

KW-0761 (product name in Japan, U.S. and Europe: POTELIGEO®)

- In June 2021, we applied for approval of its indication for treatment of mycosis fungoides and Sézary syndrome in China.

KRN125 (product name in Japan: G-Lasta®)

- In March 2021, the Company filed an application for a partial change of approval indication for the mobilization of hematopoietic stem cells into peripheral blood for allogenic blood stem cell transplantation in Japan.
- In August 2021, we applied for approval for automated injection device for decreasing the incidence of febrile neutropenia in patients receiving cancer chemotherapy in Japan.
- In September 2021, we started a phase II clinical study in Japan for the mobilization of hematopoietic stem cells into peripheral blood for autologous peripheral blood stem cell transplantation.

ME-401

- In June 2021, we started the second study arm for treatment of marginal zone lymphoma of the global phase II clinical study.
- In August 2021, we started a global phase III clinical study for combination therapy with rituximab for patients with relapsed or refractory follicular lymphoma or marginal zone lymphoma.

Immunology and allergy

KHK4083/AMG451

- In June 2021, we concluded an agreement to jointly develop and commercialize KHK4083, for the treatment of atopic dermatitis and several other diseases, with Amgen Inc.

KHK4827 (product name in Japan: LUMICEF®)

- ◆ In December 2021, we filed an application in Japan for a partial change for approval of its planned indication for systemic sclerosis.

Other**KRN23 (product name in Japan, U.S. and Europe: Crysvita®)**

- In January 2021, an application for partial change approval for our biologics license regarding its indication for treatment of tumor induced osteomalacia was accepted in Europe. (application filed in December 2020)
- In January 2021, we obtained approval of its indication for treatment of X-linked hypophosphatemic rickets and osteomalacia in China.
- In March 2021, we obtained approval of its indication for treatment of tumor induced osteomalacia in China.

AMG531 (product name in Japan: Romiplate®)














- In August 2021, we obtained approval of its indication for treatment of patients with aplastic anemia (AA) which is refractory to immunosuppressive therapy or immunosuppressive therapy being not suitable in South Korea.

R&D pipeline





 antibody
  protein
  small molecule
 © New Molecular Entity
  Updated since Dec. 31, 2020
  Updated since Sep. 30, 2021

Nephrology



As of December 31, 2021

| Code Name Generic Name Formulation | Mechanism of Action | Indication | Area | Stage | | | | | [In-House or Licensed] Remarks |
|--|---------------------------------------|---|------------|--|-------|--------|-------|----------|--|
| | | | | Ph I | Ph II | Ph III | Filed | Approved | |
|  KHK7580 Evocalcet Oral | Calcimimetic | Secondary Hyperparathyroidism | CN Asia |  | | | | | [Mitsubishi Tanabe Pharma] product name in Japan: Orkedia |
|  ©RTA 402 Bardoxolone Methyl Oral | Antioxidant Inflammation Modulator | Alport Syndrome | JP |   | | | | | [Reata] |
| | | Diabetic Kidney Disease | JP |  | | | | | |
| | | Autosomal Dominant Polycystic Kidney Disease | JP |   | | | | | |
|  KW-3357 Antithrombin Gamma Injection | Recombinant Human Antithrombin | Preeclampsia | JP |  | | | | | [In-House] product name in Japan: Acoalan |
|  KHK7791 Tenapanor Oral | NHE3 Inhibitor | Hyperphosphatemia in Patients on Dialysis | JP |   | | | | | [Ardelyx] |


Oncology

| Code Name Generic Name Formulation | Mechanism of Action | Indication | Area | Stage | | | | | [In-House or Licensed] Remarks |
|---|---|--|---|-------|-------|--------|-------|----------|--|
| | | | | Ph I | Ph II | Ph III | Filed | Approved | |
|  KW-0761 Mogamulizumab Injection | Anti-CCR4 Humanized Antibody | Mycosis Fungoides and Sézary Syndrome | CH SA AU | → | | | | | [In-House] POTELLIGENT® product name in Japan, U.S. and Europe: Poteligeo |
| | | | KR | → | | | | | |
| | | | CN CA KW | → | | | | | |
|  KRN125 Pegfilgrastim Injection | Long-Acting Granulocyte Colony-Stimulating Factor | Mobilization of Hematopoietic Stem Cells into Peripheral Blood for Allogeneic Blood Stem Cell Transplantation | JP | → | | | | | [Kirin-Amgen] product name in Japan:G-Lasta |
| | | Mobilization of Hematopoietic Stem Cells into Peripheral Blood for Autologous Blood Stem Cell Transplantation | JP | → | | | | | |
| | | Automated Injection Device for Decreasing the Incidence of Febrile Neutropenia in Patients Receiving Cancer Chemotherapy | JP | → | | | | | |
|  ©KHK2455 Oral | IDO1 Inhibitor | Solid Tumor | NA | → | | | | | [In-House] Combination with KW-0761 |
| | | Urothelial carcinoma | NA | → | | | | | [In-House] Combination with avelumab |
| | | | Europe | → | | | | | |
|  ©ME-401 Zandelisib Oral | PI3Kδ Inhibitor | Follicular Lymphoma and Marginal Zone Lymphoma | JP NA Europe Asia Oceania others | → | | | | | [ME] Pharma Combination with rituximab Second line + |
| | | Follicular Lymphoma | NA Europe Asia Oceania | → | | | | | [ME] Pharma Third line + |
| | | Marginal Zone Lymphoma | JP | → | | | | | [ME] Pharma Third line + |
| | | Indolent B-cell Non-Hodgkin's Lymphoma | JP | → | | | | | [ME] Pharma Third line + |
| | | B-cell malignancies | NA | → | | | | | [ME] Pharma Monotherapy, combination with rituximab and combination with zanubrutinib |





Immunology/Allergy

| Code Name Generic Name Formulation | Mechanism of Action | Indication | Area | Stage | | | | | [In-House or Licensed] Remarks |
|--|--|--|--------------------|-------|-------|--------|-------|----------|---|
| | | | | Ph I | Ph II | Ph III | Filed | Approved | |
|  KHK4827 Brodalumab Injection | Anti-IL-17 Receptor A Fully Human Antibody | Ankylosing Spondylitis | TW MY | → | | | | | [Kirin-Amgen] product name in Japan: Lumicef |
| | | Ankylosing Spondylitis, non-radiographic axial spondyloarthritis | TL | → | | | | | |
| | | Systemic Sclerosis | JP | → | | | | | |
| | | Palmoplantar Pustulosis | JP | → | | | | | |
|  ©KHK4083/AMG 451 Injection | Anti-OX40 Fully Human Antibody | Atopic Dermatitis | JP NA Europe | → | | | | | [In-House] POTELLIGENT® Human Antibody-Producing Technology Collaboration agreement with Amgen for the development of KHK4083/AMG 451 in all the countries except for Japan. |

Central Nervous System

| Code Name Generic Name Formulation | Mechanism of Action | Indication | Area | Stage | | | | | [In-House or Licensed] Remarks |
|---|---|---------------------|--------------|-------|-------|--------|-------|----------|---|
| | | | | Ph I | Ph II | Ph III | Filed | Approved | |
|  KW-6002 Istradefylline Oral | Adenosine A2A Receptor Antagonist | Parkinson's Disease | Europe | → | | | | | [In-House] product name in Japan:Nourias, product name in U.S.: Nouriaz |
|  ©KW-6356 Oral | Adenosine A2A Receptor Antagonist/Inverse Agonist | Parkinson's Disease | JP | → | | | | | [In-House] |
|  ©KHK6640 Injection | Anti-Amyloid Beta Peptide Antibody | Alzheimer's Disease | JP Europe | → | | | | | [Immunas Pharma] |

Other

| | Code Name Generic Name Formulation | Mechanism of Action | Indication | Area | Stage | | | | | [In-House or Licensed] Remarks | |
|---|--|------------------------------------|---|----------------------------|-------|-------|--------|-------------------|--|---|---|
| | | | | | Ph I | Ph II | Ph III | Filed | Approved | | |
|  | KRN23 Burosumab Injection | Anti-FGF23 Fully Human Antibody | X-linked Hypophosphatemia (XLH) | CN BH SA SG AU | → | → | → | → | → | [In-House] Human Antibody-Producing Technology Jointly Developed with Ultragenyx in US and EU product name in Japan, U.S. and Europe: Crysivita | |
| | | | | TL MY | → | → | → | → | → | | |
| | | | Tumor Induced Osteomalacia (TIO) | IS | → | → | → | → | → | | → |
| | | | | CA | → | → | → | → | → | | → |
| | | | | CN | → | → | → | → | → | | → |
| | | | | Europe | → | → | → | → | → | | → |
|  | AMG531 Romiplostim Injection | Thrombopoietin Receptor Agonist | Treatment of Aplastic anemia (AA) which is refractory to immunosuppressive therapy or immunosuppressive therapy being not suitable | KR | → | → | → | → | → | [Kirin-Amgen] product name in Japan: Romiplate | |
| | | | Treatment of adult aplastic anemia refractory to conventional therapies | MY SG | → | → | → | → | → | | |
| | | | Treatment of adult patients with chronic immune thrombocytopenia (ITP) who are refractory to other treatments and Treatment of adult patients with aplastic anemia who are refractory to conventional therapy | TL | → | → | → | → | → | | |
| | | | Immune Thrombocytopenia (ITP) | CN | → | → | → | → | → | | |
| | | | Aplastic Anemia Who Were Previously Untreated with Immunosuppressive Therapy | JP Asia | → | → | → | Ph II / Ph III | → | | |
|  | KW-3357 Antithrombin Gamma Injection | Recombinant Human Antithrombin | Disseminated Intravascular Coagulation, Congenital Antithrombin Deficiency | Europe | → | → | → | → | [In-House] product name in Japan: Acoalan | | |
|  | KHK4951 | | Wet Age-Related Macular Degeneration | JP | → | → | → | → | [In-House] | | |

(5) Outlook for Fiscal 2022*(Billions of yen)*

| | Fiscal year ended December 31, 2021 | Outlook for fiscal 2022 | Year-on-year change | Rate of change (%) |
|--|--|------------------------------------|------------------------|-----------------------|
| Revenue | 352.2 | 380.0 | 27.8 | 7.9% |
| Core operating profit | 65.7 | 67.0 | 1.3 | 2.0% |
| Profit before tax | 60.1 | 66.0 | 5.9 | 9.9% |
| Profit attributable to owners of parent | 52.3 | 53.0 | 0.7 | 1.2% |

Note: These forecasts assume average exchange rates of ¥110/US\$, ¥150/British pound and ¥17.1/Chinese Yuan.

Financial performance indicators

| | Fiscal year ended December 31, 2021 | Outlook for fiscal 2022 | |
|---------------------------------|--|------------------------------------|--|
| ROE | 7.3% | 7.1% | Profit / Average beginning and ending equity |
| Revenue growth ratio (CAGR) | 10.6% | 9.3% | Annual average growth rate with fiscal 2020 as base year |
| R&D expense ratio | 16.4% | 18.4% | Research and development expenses / Revenue |
| Core operating profit ratio | 18.6% | 17.6% | Core operating profit / Revenue |
| Dividend payout ratio (Note) | 43.2% | 47.9% | |

Note: The figure indicates the dividend payout ratio based on core EPS (calculated as an indicator showing recurring profitability by dividing core profit (determined by subtracting "other income," "other expenses" and the related "income tax expense" from "profit") by the average number of shares during the period).

- Consolidated financial earnings forecasts for fiscal 2022 are for revenue of ¥380.0 billion (up 7.9% compared to the current fiscal year), core operating profit of ¥67.0 billion (up 2.0%), profit before tax of ¥66.0 billion (up 9.9%), and profit attributable to owners of parent of ¥53.0 billion (up 1.2%).
- Although we expect impacts such as a reduction in drug price standards scheduled for April 2022 in Japan, revenues are expected to increase compared to the current fiscal year due to growth in the global strategic products mainly Crysvida® and an increase in licensing revenue. In addition to increases in selling, general and administrative expenses related to proactive investments in human resources and in IT/digital platform aimed at maximizing the value of global strategic products and rapidly establishing competitive global business bases, we are planning for increases in research and development expenses as a result of progress in late-stage development projects for next-generation strategic products such as KHK4083. However, we expect higher overseas revenue to lead to higher core operating profit.
- A year-on-year increase is forecasted for profit before tax as a result of a decrease in other expenses in addition to an increase in core operating profit.
- A year-on-year increase is forecasted for profit attributable to owners of parent despite an expected increase in income tax expense.
- Cash flows from operating activities are forecast to decline compared to the current fiscal year despite profit before tax being expected to increase year on year, due to the impact of changes in contract liabilities including proceeds of USD400 million in upfront payment received from Amgen Inc. based on an agreement for joint development and commercialization of KHK4083.

- Concerning cash flows from investing activities, the Company expects an increase in net cash used compared to the current fiscal year mainly because of an expected increase in cash used in the purchase of property, plant and equipment and intangible assets. Regarding strategic partnering, M&A and other strategic investments for acquiring drug discovery technologies and pipelines, the Company will evaluate and conduct investment using a flexible approach.
- Concerning cash flows from financing activities, the Company expects net cash used to be at the same level as the current fiscal year. As regards the purchase of treasury shares and the sourcing of funds, we will remain flexible and act as appropriate for the economic and funding environment.

As a result of the above, cash and cash equivalents as of the end of fiscal 2022 are expected to be at the same level as at the end of fiscal 2021.

Note: The above financial position outlook is based on information available to management at the current time. As such, they do not constitute guarantees by the Company of future performance. Actual results may differ materially from these projections for a wide variety of reasons.

(6) Basic Policy on Profit Distribution: Fiscal 2021 and Fiscal 2022 Dividends

The Company regards the return of profits to its shareholders as one of its key management priorities. The basis of the Company's policy regarding the distribution of profits is to pay dividends stably in light of a comprehensive consideration of factors including consolidated results and dividend payout ratio for each fiscal year, while also increasing its retained earnings for future business development and other purposes. We plan to improve our capital efficiency with regards to the purchase of treasury shares by taking a flexible approach while considering the share price in the market and other factors. The Company considers it a top priority to use internal reserve funds for investments for future growth (R&D investments, strategic investments and capital expenditures) in order to achieve sustainable growth from fiscal 2025 and maximize corporate value.

As the dividend policy, the Company set its target dividend payout ratio based on core EPS at 40% in the FY2021-2025 Mid-term Business Plan. The Company aims to ensure a stable and sustained increase in the level of dividend payment (continuous increase of dividend payments) in line with medium- to long-term growth in profits.

In accordance with the above-mentioned policy, the Board of Directors has resolved to pay a year-end dividend for fiscal 2021 of ¥23 per share. As a result, we expect to increase dividends for the fifth year in a row. The annual dividend is expected to be ¥46, an increase of ¥2 compared to the previous fiscal year, including an interim dividend of ¥23. With respect to the year-end dividend, we plan to submit a proposal at the 99th Ordinary General Meeting of Shareholders to be held on March 25, 2022.

Dividends of Surplus

| | Details of resolution (March 25, 2022) | Dividend forecast most recently announced (Announced on February 4, 2021) | Fiscal 2020 results (Fiscal year ended December 31, 2020) |
|--|---|--|---|
| Record date | December 31, 2021 | Same as left | December 31, 2020 |
| Dividend per share (Yen) | 23.00 | 23.00 | 22.00 |
| Total dividend amount (Millions of yen) | 12,359 | – | 11,818 |
| Effective date | March 28, 2022 | – | March 25, 2021 |
| Dividend resource | Retained earnings | – | Retained earnings |

(Reference) Breakdown of Dividends per Share

(Yen)

| | Fiscal 2021 (Fiscal year ended December 31, 2021) | Dividend forecast most recently announced (Announced on February 4, 2021) | Fiscal 2020 results (Fiscal year ended December 31, 2020) |
|----------------------|---|--|---|
| [Second quarter-end] | [23.00] | [23.00] | [22.00] |
| Fiscal year-end | 23.00 (Note) | 23.00 | 22.00 |
| Dividends per share | 46.00 | 46.00 | 44.00 |

Note: The fiscal year-end dividend (¥23.00) for the current term (fiscal year ended December 31, 2021) is based on the assumption that it will be approved at the 99th Ordinary General Meeting of Shareholders scheduled to be held on March 25, 2022.

For the fiscal year ending December 31, 2022, we expect to pay an annual dividend of ¥48 per share, an increase of ¥2 compared to the current fiscal year, consisting of an interim dividend of ¥24 and a year-end dividend of ¥24. For details of the "core EPS," refer to "(5) Outlook for Fiscal 2022."

2. Basic Rationale for Selection of Accounting Standards

The Group has applied IFRS from fiscal 2017 to enhance the international comparability of its financial information in the capital markets, and unify the process of the Group's accounting.

3. Consolidated Financial Statements and Significant Notes Thereto**(1) Consolidated Statement of Financial Position***(Millions of yen)*

| | As of December 31, 2020 | As of December 31, 2021 |
|---|----------------------------|----------------------------|
| Assets | | |
| Non-current assets | | |
| Property, plant and equipment | 76,012 | 78,652 |
| Goodwill | 132,695 | 136,352 |
| Intangible assets | 75,027 | 76,066 |
| Investments accounted for using equity method | 9,475 | — |
| Other financial assets | 17,323 | 45,164 |
| Retirement benefit asset | 14,674 | 15,298 |
| Deferred tax assets | 33,133 | 49,108 |
| Other non-current assets | 468 | 3,000 |
| Total non-current assets | 358,808 | 403,641 |
| Current assets | | |
| Inventories | 51,281 | 64,089 |
| Trade and other receivables | 92,287 | 104,275 |
| Other financial assets | 636 | 1,434 |
| Other current assets | 6,161 | 13,350 |
| Cash and cash equivalents | 287,019 | 335,084 |
| Subtotal | 437,385 | 518,231 |
| Assets held for sale | 5,097 | — |
| Total current assets | 442,482 | 518,231 |
| Total assets | 801,290 | 921,872 |

(1) Consolidated Statement of Financial Position (continued)*(Millions of yen)*

| | As of December 31, 2020 | As of December 31, 2021 |
|---|----------------------------|----------------------------|
| Equity | | |
| Share capital | 26,745 | 26,745 |
| Capital surplus | 463,967 | 464,153 |
| Treasury shares | (3,545) | (3,359) |
| Retained earnings | 226,639 | 255,528 |
| Other components of equity | (15,410) | (5,904) |
| Total equity attributable to owners of parent | 698,396 | 737,162 |
| Total equity | 698,396 | 737,162 |
| Liabilities | | |
| Non-current liabilities | | |
| Liabilities from application of equity method | – | 19,426 |
| Retirement benefit liability | 216 | 221 |
| Provisions | 7,823 | 7,757 |
| Deferred tax liabilities | 92 | 386 |
| Other financial liabilities | 13,159 | 16,594 |
| Other non-current liabilities | 854 | 31,197 |
| Total non-current liabilities | 22,145 | 75,581 |
| Current liabilities | | |
| Trade and other payables | 54,867 | 64,652 |
| Provisions | 2,027 | 1,580 |
| Other financial liabilities | 5,123 | 5,943 |
| Income taxes payable | 4,661 | 13,426 |
| Other current liabilities | 14,070 | 23,528 |
| Total current liabilities | 80,749 | 109,129 |
| Total liabilities | 102,894 | 184,710 |
| Total equity and liabilities | 801,290 | 921,872 |

(2) Consolidated Statement of Profit or Loss and Consolidated Statement of Comprehensive Income**Consolidated Statement of Profit or Loss***(Millions of yen)*

| | Fiscal year ended December 31, 2020 | Fiscal year ended December 31, 2021 |
|---|--|--|
| Revenue | 318,352 | 352,246 |
| Cost of sales | (80,440) | (87,849) |
| Gross profit | 237,912 | 264,398 |
| Selling, general and administrative expenses | (126,610) | (145,608) |
| Research and development expenses | (52,312) | (57,679) |
| Share of profit (loss) of investments accounted for using equity method | 964 | 4,575 |
| Other income | 1,651 | 985 |
| Other expenses | (10,842) | (6,616) |
| Finance income | 1,798 | 1,113 |
| Finance costs | (299) | (1,117) |
| Profit before tax | 52,263 | 60,050 |
| Income tax expense | (5,236) | (7,703) |
| Profit | 47,027 | 52,347 |
| Profit attributable to Owners of parent | 47,027 | 52,347 |
| Earnings per share | | |
| Basic earnings per share (Yen) | 87.56 | 97.43 |
| Diluted earnings per share (Yen) | 87.50 | 97.39 |

Consolidated Statement of Comprehensive Income*(Millions of yen)*

| | Fiscal year ended December 31, 2020 | Fiscal year ended December 31, 2021 |
|---|--|--|
| Profit | 47,027 | 52,347 |
| Other comprehensive income | | |
| Items that will not be reclassified to profit or loss | | |
| Financial assets measured at fair value through other comprehensive income | (1,138) | (1,623) |
| Remeasurements of defined benefit plans | 2,021 | 1,411 |
| Share of other comprehensive income of investments accounted for using equity method | (31) | – |
| Total of items that will not be reclassified to profit or loss | 852 | (212) |
| Items that may be reclassified to profit or loss | | |
| Exchange differences on translation of foreign operations | (4,156) | 10,498 |
| Share of other comprehensive income of investments accounted for using equity method | (112) | 118 |
| Total of items that may be reclassified to profit or loss | (4,268) | 10,616 |
| Other comprehensive income | (3,416) | 10,404 |
| Comprehensive income | 43,611 | 62,751 |
| Comprehensive income attributable to Owners of parent | 43,611 | 62,751 |

(3) Consolidated Statement of Changes in Equity

Fiscal year ended December 31, 2020

(Millions of yen)

| | Equity attributable to owners of parent | | | | | |
|---|---|-----------------|-----------------|-------------------|----------------------------|---|
| | Share capital | Capital surplus | Treasury shares | Retained earnings | Other components of equity | |
| | | | | | Share acquisition rights | Exchange differences on translation of foreign operations |
| Balance at January 1, 2020 | 26,745 | 463,893 | (3,792) | 201,253 | 751 | (13,647) |
| Profit | – | – | – | 47,027 | – | – |
| Other comprehensive income | – | – | – | – | – | (4,268) |
| Total comprehensive income | – | – | – | 47,027 | – | (4,268) |
| Dividends of surplus | – | – | – | (23,631) | – | – |
| Purchase of treasury shares | – | – | (14) | – | – | – |
| Disposal of treasury shares | – | 19 | 171 | – | – | – |
| Share-based remuneration transactions | – | 55 | 91 | – | (155) | – |
| Transfer from other components of equity to retained earnings | – | – | – | 1,990 | – | – |
| Total transactions with owners | – | 74 | 247 | (21,641) | (155) | – |
| Balance at December 31, 2020 | 26,745 | 463,967 | (3,545) | 226,639 | 596 | (17,915) |

| | Equity attributable to owners of parent | | | | | Total equity |
|---|--|---|----------|----------|----------|--------------|
| | Other components of equity | | | Total | Total | |
| | Financial assets measured at fair value through other comprehensive income | Remeasurements of defined benefit plans | Total | | | |
| Balance at January 1, 2020 | 3,047 | – | (9,849) | 678,250 | 678,250 | |
| Profit | – | – | – | 47,027 | 47,027 | |
| Other comprehensive income | (1,138) | 1,990 | (3,416) | (3,416) | (3,416) | |
| Total comprehensive income | (1,138) | 1,990 | (3,416) | 43,611 | 43,611 | |
| Dividends of surplus | – | – | – | (23,631) | (23,631) | |
| Purchase of treasury shares | – | – | – | (14) | (14) | |
| Disposal of treasury shares | – | – | – | 190 | 190 | |
| Share-based remuneration transactions | – | – | (155) | (10) | (10) | |
| Transfer from other components of equity to retained earnings | (0) | (1,990) | (1,990) | – | – | |
| Total transactions with owners | (0) | (1,990) | (2,145) | (23,465) | (23,465) | |
| Balance at December 31, 2020 | 1,909 | – | (15,410) | 698,396 | 698,396 | |

(3) Consolidated Statement of Changes in Equity (continued)

Fiscal year ended December 31, 2021

(Millions of yen)

| | Equity attributable to owners of parent | | | | | |
|---|---|-----------------|-----------------|-------------------|----------------------------|---|
| | Share capital | Capital surplus | Treasury shares | Retained earnings | Other components of equity | |
| | | | | | Share acquisition rights | Exchange differences on translation of foreign operations |
| Balance at January 1, 2021 | 26,745 | 463,967 | (3,545) | 226,639 | 596 | (17,915) |
| Profit | – | – | – | 52,347 | – | – |
| Other comprehensive income | – | – | – | – | – | 10,616 |
| Total comprehensive income | – | – | – | 52,347 | – | 10,616 |
| Dividends of surplus | – | – | – | (24,176) | – | – |
| Purchase of treasury shares | – | – | (23) | – | – | – |
| Disposal of treasury shares | – | 61 | 121 | – | – | – |
| Share-based remuneration transactions | – | 126 | 88 | – | (181) | – |
| Transfer from other components of equity to retained earnings | – | – | – | 717 | – | – |
| Total transactions with owners | – | 187 | 186 | (23,459) | (181) | – |
| Balance at December 31, 2021 | 26,745 | 464,153 | (3,359) | 255,528 | 414 | (7,299) |

| | Equity attributable to owners of parent | | | | Total equity |
|---|--|---|----------|----------|--------------|
| | Other components of equity | | | Total | |
| | Financial assets measured at fair value through other comprehensive income | Remeasurements of defined benefit plans | Total | | |
| Balance at January 1, 2021 | 1,909 | – | (15,410) | 698,396 | 698,396 |
| Profit | – | – | – | 52,347 | 52,347 |
| Other comprehensive income | (1,623) | 1,411 | 10,404 | 10,404 | 10,404 |
| Total comprehensive income | (1,623) | 1,411 | 10,404 | 62,751 | 62,751 |
| Dividends of surplus | – | – | – | (24,176) | (24,176) |
| Purchase of treasury shares | – | – | – | (23) | (23) |
| Disposal of treasury shares | – | – | – | 182 | 182 |
| Share-based remuneration transactions | – | – | (181) | 32 | 32 |
| Transfer from other components of equity to retained earnings | 694 | (1,411) | (717) | – | – |
| Total transactions with owners | 694 | (1,411) | (898) | (23,985) | (23,985) |
| Balance at December 31, 2021 | 980 | – | (5,904) | 737,162 | 737,162 |

(4) Consolidated Statement of Cash Flows*(Millions of yen)*

| | Fiscal year ended December 31, 2020 | Fiscal year ended December 31, 2021 |
|--|--|--|
| Cash flows from operating activities | | |
| Profit before tax | 52,263 | 60,050 |
| Depreciation and amortization | 20,466 | 19,498 |
| Impairment losses | 2,857 | 5,286 |
| Increase (decrease) in provisions | 2,667 | (608) |
| Share of loss (profit) of investments accounted for using equity method | (964) | (4,575) |
| Decrease (increase) in inventories | (6,587) | (8,280) |
| Decrease (increase) in trade receivables | (5,654) | (5,901) |
| Increase (decrease) in trade payables | 2,553 | (126) |
| Increase (decrease) in contract liabilities | (1,559) | 38,767 |
| Income taxes paid | (28,662) | (14,838) |
| Other | 2,121 | (2,727) |
| Net cash provided by (used in) operating activities | 39,502 | 86,548 |
| Cash flows from investing activities | | |
| Purchase of property, plant and equipment | (10,115) | (6,522) |
| Purchase of intangible assets | (25,112) | (13,244) |
| Purchase of investments accounted for using equity method | (500) | – |
| Proceeds from sale of investments accounted for using equity method | – | 5,097 |
| Proceeds from sale of investment securities | – | 1,914 |
| Proceeds from capital reduction with compensation of investment securities | 1,500 | – |
| Net decrease (increase) in loans receivable from parent | 285,631 | – |
| Other | 1,155 | 1,393 |
| Net cash provided by (used in) investing activities | 252,559 | (11,363) |
| Cash flows from financing activities | | |
| Repayments of lease liabilities | (3,175) | (3,475) |
| Purchase of treasury shares | (14) | (23) |
| Dividends paid | (23,631) | (24,176) |
| Other | 817 | (771) |
| Net cash provided by (used in) financing activities | (26,003) | (28,446) |
| Effect of exchange rate changes on cash and cash equivalents | 199 | 1,325 |
| Net increase (decrease) in cash and cash equivalents | 266,257 | 48,065 |
| Cash and cash equivalents at beginning of period (Amount on the consolidated statement of financial position) | 20,762 | 287,019 |
| Cash and cash equivalents at beginning of period | 20,762 | 287,019 |
| Cash and cash equivalents at end of period | 287,019 | 335,084 |

(5) Notes to Consolidated Financial StatementsNotes on going concern assumption

No applicable items.

Segment information, etc.

(1) Outline of reportable segments

The Group omitted information by reportable segment as the Group consists of only the one reportable segment, which is the Pharmaceuticals business.

(2) Information about products and services

Breakdown of revenue from external customers by product and service is as follows.

(Millions of yen)

| | Fiscal year ended December 31, 2020 | Fiscal year ended December 31, 2021 |
|-------------------|--|--|
| Products | 298,827 | 326,141 |
| Licensing revenue | 19,525 | 26,105 |
| Total | 318,352 | 352,246 |

(3) Information about geographical areas

i. Revenue

(Millions of yen)

| | Fiscal year ended December 31, 2020 | Fiscal year ended December 31, 2021 |
|--------------------|--|--|
| Japan | 166,639 | 161,988 |
| Americas | 72,178 | 102,163 |
| Of which, the U.S. | 70,331 | 99,328 |
| Europe | 48,530 | 53,361 |
| Asia | 30,848 | 34,518 |
| Other | 156 | 217 |
| Total | 318,352 | 352,246 |

Note: Revenue is classified by region or country based on location of customer.

ii. Non-current assets

(Millions of yen)

| | As of December 31, 2020 | As of December 31, 2021 |
|----------|-------------------------|-------------------------|
| Japan | 226,109 | 227,854 |
| Americas | 7,727 | 11,526 |
| Europe | 47,704 | 51,669 |
| Asia | 2,663 | 3,021 |
| Total | 284,203 | 294,070 |

Note: Non-current assets are classified based on the location of assets, and do not include investments accounted for using the equity method, financial instruments, retirement benefit asset and deferred tax assets.

(4) Information about major customers

The customer that accounts for 10% or more of revenue in the consolidated statement of profit or loss is as follows:

(Millions of yen)

| Customer | Fiscal year ended December 31, 2020 | Fiscal year ended December 31, 2021 |
|----------------------------|--|--|
| Alfresa Pharma Corporation | 40,219 | 35,123 |

Per share information

| | Fiscal year ended December 31, 2020 | Fiscal year ended December 31, 2021 |
|--|--|--|
| Profit attributable to ordinary equity holders of parent | | |
| Profit attributable to owners of parent (Millions of yen) | 47,027 | 52,347 |
| Profit not attributable to ordinary equity holders of parent (Millions of yen) | – | – |
| Profit used for calculation of earnings per share (Millions of yen) | 47,027 | 52,347 |
| Average number of ordinary shares outstanding during period (Shares) | 537,109,444 | 537,272,070 |
| Increase in number of ordinary shares | | |
| Share acquisition rights (Shares) | 368,934 | 242,100 |
| Average number of diluted ordinary shares outstanding during period (Shares) | 537,478,378 | 537,514,170 |
| Earnings per share | | |
| Basic earnings per share (Yen) | 87.56 | 97.43 |
| Diluted earnings per share (Yen) | 87.50 | 97.39 |

Significant subsequent events

No applicable items.