Kyowa Kirin Co., Ltd.

Consolidated Financial Summary (IFRS)
Fiscal 2024 Third Quarter

(January 1, 2024 – September 30, 2024)

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

SUMMARY OF CONSOLIDATED FINANCIAL STATEMENTS (IFRS)
for Nine Months Ended September 30, 2024

October 31, 2024

Company Name: Kyowa Kirin Co., Ltd.
Listed Exchanges: Tokyo Stock Exchange
Stock Code: 4151
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Inquiries: Hiroki Nakamura
Executive Vice President,
Corporate Communications Department
URL: https://www.kyowakirin.com/index.html
Scheduled start date of dividend payment: –
Appendix materials to accompany the financial report: Yes
Results presentation meeting: Yes (for institutional investors and securities analysts)

(Millions of yen rounded off)

1. Consolidated Financial Results for the Nine Months Ended September 30, 2024

(1) Consolidated operating results

(Percentages indicate year-on-year changes.)

	Revenue		Core operating profit		Profit before tax		Profit	
Nine months ended	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
September 30, 2024	362,798	18.5	74,416	22.2	71,573	11.2	55,901	4.4
September 30, 2023	306,053	7.9	60,872	0.0	64,339	6.5	53,554	8.8

Total comprehensive income: Nine months ended September 30, 2024: ¥66,170 million; (15.1)%
Nine months ended September 30, 2023: ¥77,963 million; 53.6%

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
Nine months ended	Millions of yen	%	Yen	Yen
September 30, 2024	55,901	4.4	105.20	105.19
September 30, 2023	53,554	8.8	99.62	99.61

(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
As of	Millions of yen	Millions of yen	Millions of yen	%
September 30, 2024	1,041,966	835,248	835,248	80.2
December 31, 2023	1,025,942	836,418	836,418	81.5

2. Dividends

	Dividends per share				
	First quarter-end	Second quarter-end	Third quarter-end	Fiscal year-end	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal year ended December 31, 2023	–	27.00	–	29.00	56.00
Fiscal year ending December 31, 2024	–	29.00	–		
Fiscal year ending December 31, 2024 (Forecast)				29.00	58.00

Note: Revisions to the dividend forecast most recently announced: None

3. Consolidated Earnings Forecasts for the Fiscal Year Ending December 31, 2024 (from January 1, 2024 to December 31, 2024)

(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	492,000	11.3	92,000	(4.9)	92,000	(5.3)	68,000	(16.2)	68,000	(16.2)	128.42

Note: Changes to the earnings forecasts most recently announced: None

*** Notes**

(1) Significant changes in the scope of consolidation during the period under review: Yes

Newly included: one company	Orchard Therapeutics plc
Excluded: one company	Kyowa Kirin China Pharmaceutical Co., Ltd.

(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 September 30, 2024	540,000,000 shares
As of December 31, 2023	540,000,000 shares

b. Number of treasury shares

As of September 30, 2024	15,278,212 shares
As of December 31, 2023	2,390,712 shares

c. Average number of shares during the period

Nine months ended September 30, 2024	531,380,426 shares
Nine months ended September 30, 2023	537,565,293 shares

* Review of the Japanese-language originals of the attached quarterly consolidated financial statements by certified public accountants or an audit corporation: None

* 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.

Attachment Index

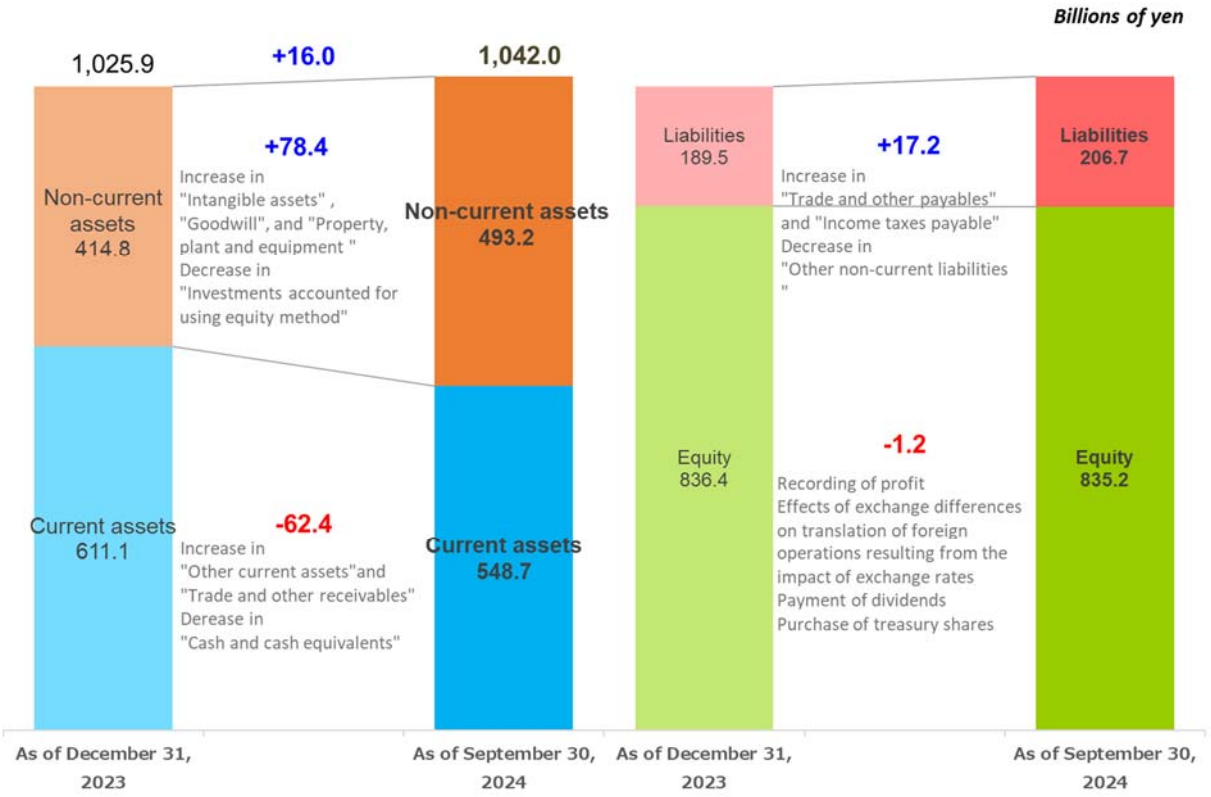
1. Summary of Business Performance and Financial Position

(1) Summary of Consolidated Financial Position for the Period

(Billions of yen)

	As of December 31, 2023	As of September 30, 2024	Year-on-year change
Assets	1,025.9	1,042.0	16.0
Non-current assets	414.8	493.2	78.4
Current assets	611.1	548.7	(62.4)
Liabilities	189.5	206.7	17.2
Equity	836.4	835.2	(1.2)
Ratio of equity attributable to owners of parent to total assets (%)	81.5%	80.2%	(1.3)%

- Assets as of September 30, 2024, were ¥1,042.0 billion, an increase of ¥16.0 billion compared to the end of the previous fiscal year.
  - Non-current assets increased by ¥78.4 billion compared to the end of the previous fiscal year, to ¥493.2 billion, due mainly to an increase in goodwill and intangible assets as a result of the business combination associated with the acquisition of shares of Orchard Therapeutics plc, in addition to the purchase of intangible assets through the introduction of development products and the purchase of property, plant and equipment, despite factors such as a decrease in investments accounted for using equity method.
  - Current assets decreased by ¥62.4 billion compared to the end of the previous fiscal year, to ¥548.7 billion, due mainly to a decrease in cash and cash equivalents, despite increases in trade and other receivables and other current assets.
- Liabilities as of September 30, 2024, were ¥206.7 billion, an increase of ¥17.2 billion compared to the end of the previous fiscal year, due mainly to increases in trade and other payables and income taxes payable, despite factors such as a decrease in other non-current liabilities due to a decrease in contract liabilities.
- Equity as of September 30, 2024, was ¥835.2 billion, a decrease of ¥1.2 billion compared to the end of the previous fiscal year, due mainly to a decrease due to the payment of dividends, in addition to the purchase of treasury shares, despite 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. As a result, the ratio of equity attributable to owners of parent to total assets as of September 30, 2024 was 80.2%, a decrease of 1.3 percentage points compared to the end of the previous fiscal year.


Billions of yen
1,025.9
+16.0
1,042.0
Non-current assets 414.8
+78.4
Increase in "Intangible assets" , "Goodwill", and "Property, plant and equipment " Decrease in "Investments accounted for using equity method"
Non-current assets 493.2
Current assets 611.1
-62.4
Increase in "Other current assets"and "Trade and other receivables" Derease in "Cash and cash equivalents"
Current assets 548.7
As of December 31, 2023
As of September 30, 2024
Liabilities 189.5
+17.2
Increase in "Trade and other payables" and "Income taxes payable" Decrease in "Other non-current liabilities "
Liabilities 206.7
Equity 836.4
-1.2
Recording of profit
Effects of exchange differences on translation of foreign operations resulting from the impact of exchange rates
Payment of dividends
Purchase of treasury shares
Equity 835.2
As of December 31, 2023
As of September 30, 2024

(2) Summary of Business Performance in the Period

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)

	Nine months ended September 30, 2023	Nine months ended September 30, 2024	Year-on-year change	Rate of change (%)
Revenue	306.1	362.8	56.7	18.5%
Core operating profit	60.9	74.4	13.5	22.2%
Profit before tax	64.3	71.6	7.2	11.2%
Profit attributable to owners of parent	53.6	55.9	2.3	4.4%

< Average exchange rates for each period >

Currency	Nine months ended September 30, 2023	Nine months ended September 30, 2024	Year-on-year change
USD (USD/¥)	¥137	¥151	Up ¥14
GBP (GBP/¥)	¥170	¥193	Up ¥23
EUR (EUR/¥)	¥148	¥164	Up ¥16

For the nine months ended September 30, 2024 (January 1, 2024 to September 30, 2024), revenue was ¥362.8 billion (up 18.5% compared to the same period of the previous fiscal year), and core operating profit was ¥74.4 billion (up 22.2%). Profit attributable to owners of parent was ¥55.9 billion (up 4.4%).

- The increase in revenue was the result of growth of global strategic products mainly in North America and a rise in revenue from technology out-licensing. The positive effect on revenue from foreign exchange was ¥23.3 billion.
- Core operating profit increased as a result of higher gross profit achieved due to gains in overseas revenue and revenue from technology out-licensing, despite significantly higher research and development expenses. The positive effect on core operating profit from foreign exchange was ¥8.4 billion.
- Profit attributable to owners of parent increased as a result of an increase in core operating profit, despite a decrease in other income due mainly to a decrease in gain on sale of investments in subsidiaries, as well as an increase in income tax expense.

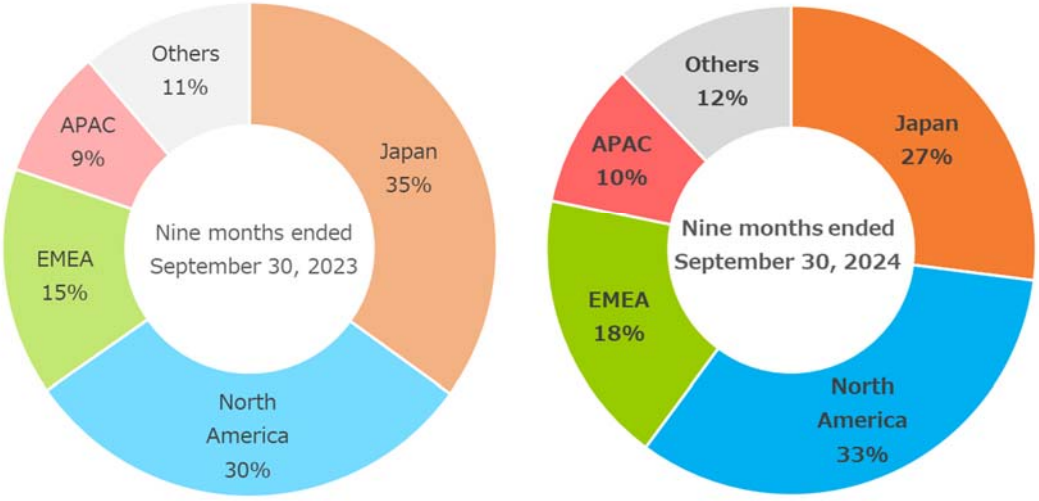
2) Revenue by regional control function

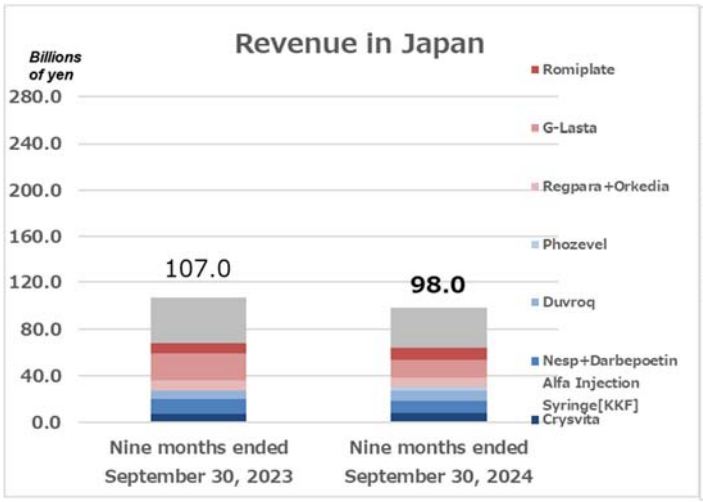
(Billions of yen)

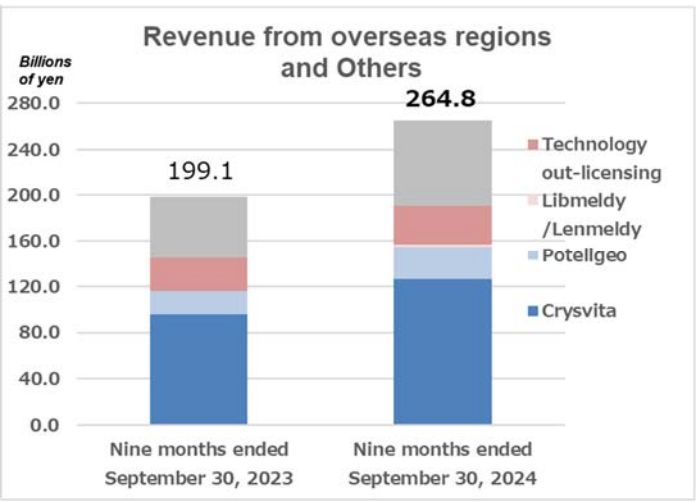
	Nine months ended September 30, 2023	Nine months ended September 30, 2024	Year-on-year change	Rate of change (%)
Japan	107.0	98.0	(8.9)	(8.3)%
North America	92.9	120.1	27.2	29.3%
EMEA	45.7	65.7	20.0	43.7%
APAC	26.0	35.0	9.0	34.7%
Others	34.5	43.9	9.5	27.5%
Total consolidated revenue	306.1	362.8	56.7	18.5%

Notes:
1. Revenue by regional control function is classified based on consolidated revenue from products of regional control functions in the One Kyowa Kirin (OKK) matrix global management structure, which combines a regional organization based on four regions of Japan, North America, EMEA and APAC, a functional organization, and a product organization (product franchises).
2. EMEA consists of Europe, the Middle East, Africa, etc.
3. APAC includes revenue from supplying products to partners in that region.
4. Others consists of revenue from technology out-licensing, hematopoietic stem cell gene therapy (revenue from Orchard Therapeutics plc), original equipment manufacturing, etc.

Composition of revenue by regional control function







< Revenue in Japan region >

(Billions of yen)

	Nine months ended September 30, 2023	Nine months ended September 30, 2024	Year-on-year change	Rate of change (%)
Crysvita	7.4	8.2	0.8	10.6%
Darbepoetin Alfa Injection Syringe [KKF]	10.3	8.5	(1.9)	(18.3)%
Duvroq	6.9	8.9	2.1	30.1%
PHOZEVEL	–	2.9	2.9	–
G-Lasta	23.2	15.3	(7.9)	(34.1)%

- Revenue in Japan decreased year on year due mainly to the impact of the reductions in drug price standards implemented in April 2023 and April 2024, despite the growth in sales of Duvroq, a treatment for renal anemia, and the launch of PHOZEVEL, a treatment for hyperphosphatemia.
  - Revenue from Crysvita, a treatment for FGF23-related diseases, has been growing steadily since its launch in 2019.
  - Revenue from Darbepoetin Alfa Injection Syringe [KKF], a treatment for renal anemia, decreased due to the impact of the reductions in drug price standards and the market penetration of rival products.
  - Revenue from Duvroq, a treatment for renal anemia, has been growing steadily since its launch in 2020.
  - Revenue from PHOZEVEL, a treatment for hyperphosphatemia launched in February 2024, has been growing steadily as a result of penetrating the market.
  - Revenue from G-Lasta, an agent for decreasing the incidence of febrile neutropenia, decreased due to the impact of biosimilar products launched in November 2023 and the impact of the reductions in drug price standards.

<Revenue from overseas regions and Others>

(Billions of yen)

	Nine months ended September 30, 2023	Nine months ended September 30, 2024	Year-on-year change	Rate of change (%)
Crysvita	95.7	126.7	31.0	32.3%
Poteligeo	19.9	27.7	7.8	39.3%
Libmeldy/Lenmeldy	–	2.2	2.2	–

- Revenue in North America increased year on year due to the growth of global strategic products.
  - Revenue from Crysvita, a treatment for X-linked hypophosphatemia, has been growing steadily since its launch in 2018.
  - Revenue from Poteligeo, an anticancer agent, has been growing since its launch in 2018.

- Revenue in EMEA increased year on year due to factors such as growth of global strategic products and proceeds from transfer of rights to three brands (Abstral, Adcal D3 and Sancuso), despite a drop in revenue from the established medicines.
  - Revenue from Crysvita, a treatment for X-linked hypophosphatemia, has been growing since its launch in 2018, as the number of countries where it has been released and its indications have expanded.
  - Revenue from Poteligeo, an anticancer agent, has been growing as the number of countries where it has been released has been increasing since its launch in 2020.
  - Following the shift to a joint venture with Grünenthal GmbH for the established medicines business, revenue from established medicines decreased as revenue for 13 brands shifted from product sales to sales royalties and license fees in August 2023 and also as sales royalties for three of those brands ended in July 2024.

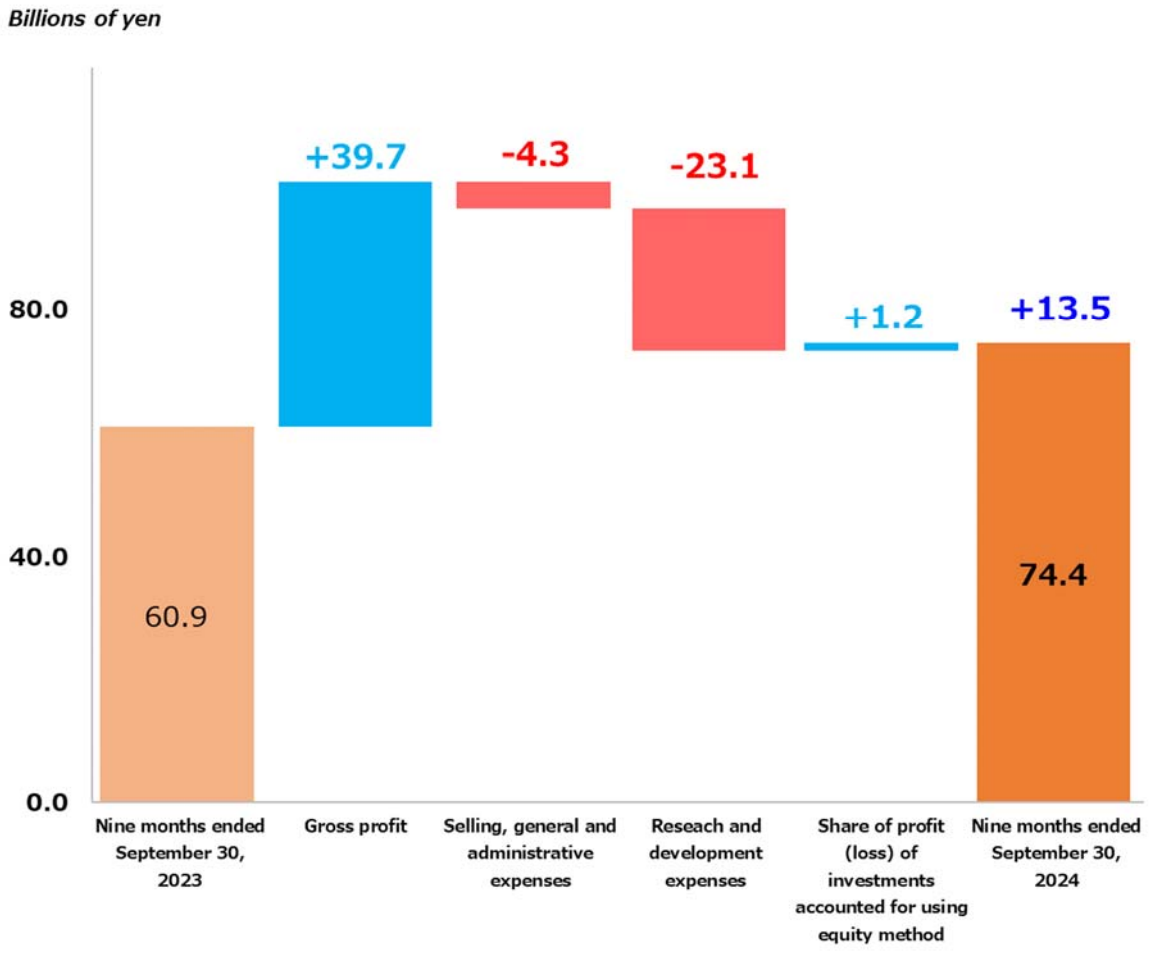
- Revenue of £66.4 million (¥13.1 billion) was recorded in July 2024 due to the transfer of the rights (intellectual property) for three brands of established medicines to the joint venture.

- Revenue in APAC increased year on year.
  - Revenue from Crysvita, a treatment for X-linked hypophosphatemia, has been growing steadily.
  - In conjunction with the business restructuring in the APAC region, revenue increased due to supplying the licensees with the inventories of established medicines from the subsidiaries in South Korea and Taiwan at the end of September 2024.

- Revenue from Others increased year on year.
  - As a result of the new consolidation of Orchard Therapeutics plc, revenue was recorded for Libmeldy (approval was obtained in the United States in March 2024 under the product name of Lenmeldy), which is sold by that company in Europe for treatment of metachromatic leukodystrophy (MLD).
  - Revenue increased due to an increase in royalties revenue from AstraZeneca in relation to benralizumab and the proceeds from an upfront payment from Boehringer Ingelheim.

3) Core operating profit

- Core operating profit increased year on year due to growth in revenue from global strategic products mainly in North America and a rise in gross profit from revenue from technology out-licensing, despite a significant increase in research and development expenses as a result of progress in development for KHK4083, for which a multiregional phase III clinical trial is ongoing, and the new consolidation of Orchard Therapeutics plc.

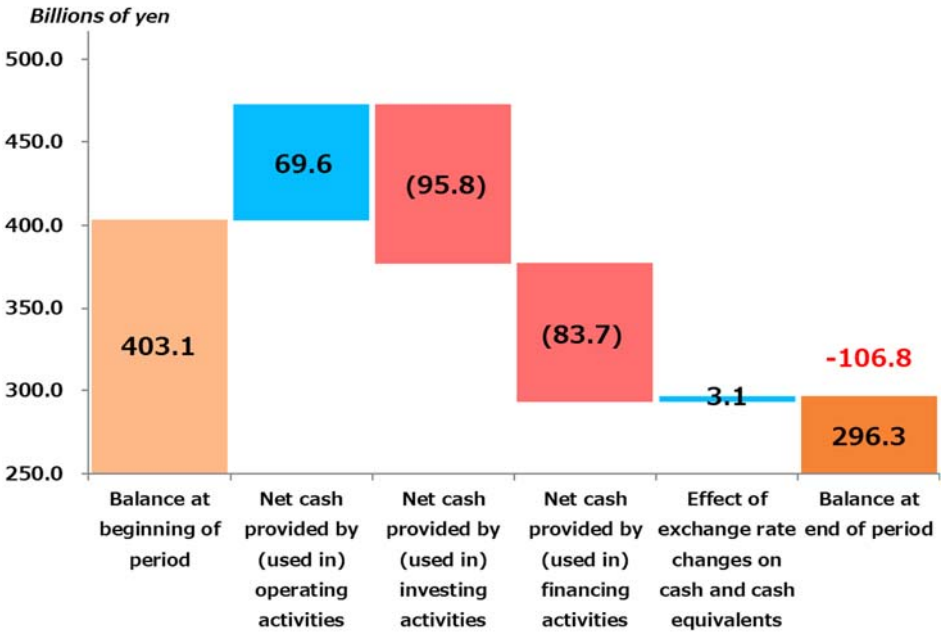


(3) Cash Flow Summary for the Period

(Billions of yen)

	Nine months ended September 30, 2023	Nine months ended September 30, 2024	Year-on-year change	Rate of change (%)
Net cash provided by (used in) operating activities	84.3	69.6	(14.7)	(17.4)%
Net cash provided by (used in) investing activities	(12.5)	(95.8)	(83.3)	666.9%
Net cash provided by (used in) financing activities	(31.4)	(83.7)	(52.3)	166.5%
Cash and cash equivalents at beginning of period	339.2	403.1	63.9	18.8%
Cash and cash equivalents at end of period	382.3	296.3	(85.9)	(22.5)%

- Cash and cash equivalents as of September 30, 2024 were ¥296.3 billion, a decrease of ¥106.8 billion compared with the balance of ¥403.1 billion as of December 31, 2023.
  The main contributing factors affecting cash flow during the nine months ended September 30, 2024 were as follows:
- Net cash provided by operating activities was ¥69.6 billion, compared with net cash provided by operating activities of ¥84.3 billion in the same period of the previous fiscal year. Major inflows were depreciation and amortization of ¥18.8 billion and foreign exchange loss (gain) of ¥7.3 billion mainly relating to exchange differences on translation of foreign currency denominated deposits from consolidated subsidiaries as of September 30, 2024, in addition to profit before tax of ¥71.6 billion. Major outflows were an increase in trade receivables of ¥15.7 billion, income taxes paid of ¥12.3 billion, a decrease of contract liabilities of ¥7.9 billion, and gain on sale of investments in subsidiaries of ¥7.8 billion.
- Net cash used in investing activities was ¥95.8 billion, compared with net cash used in investing activities of ¥12.5 billion in the same period of the previous fiscal year. Major outflows were ¥48.2 billion for the acquisition of shares of Orchard Therapeutics plc, purchase of intangible assets of ¥25.6 billion, and purchase of property, plant and equipment of ¥18.6 billion. A major inflow was proceeds from sale of property, plant and equipment of ¥3.4 billion.
- Net cash used in financing activities was ¥83.7 billion, compared with net cash used in financing activities of ¥31.4 billion in the same period of the previous fiscal year. Major outflows were a purchase of treasury shares of ¥36.4 billion, dividends paid of ¥30.9 billion, redemption of bonds with share acquisition rights issued by Orchard Therapeutics plc of ¥9.6 billion, and an increase in deposits for the purchase of treasury shares of ¥3.6 billion.



(4) Research and Development Activities

The Group continuously and actively invests resources in research and development activities. The Group aims to continually create new drugs with life-changing value by including bone and mineral, intractable hematological diseases and hemato oncology, and rare disease in the disease science field in which it focuses its in-house research and development, and, with regard to drug discovery technology, strengthening innovative modalities such as advanced antibody technologies and hematopoietic stem cell gene therapy. The Group will also continue to promote open innovation activities, collaborate with partners, invest in venture capital funds, and engage in corporate venture capital activities. The Group choses an appropriate business model with life-changing value created, promotes the development of assets in focus disease areas with the aim of expanding them globally. At the same time, for assets outside of the disease areas of focus disease areas, the Group achieves value maximization through strategic collaboration with external partners.

For the nine months ended September 30, 2024, the Group's research and development expenses totaled ¥74.3 billion.

<Development status of major development products>

As of September 30, 2024

Code, Generic Name	Indication	Development status
rocatinlimab	Moderate and severe atopic dermatitis	Ph III clinical study: in progress
	Prurigo nodularis	Ph III clinical study: in progress
	Moderate and severe asthma	Ph II clinical study: in progress
KHK4951,tivozanib	Neovascular Age-related Macular Degeneration (nAMD)	Ph II clinical study: in progress
	Diabetic Macular Edema (DME)	Ph II clinical study: in progress
KK4277	Systemic Erythematosus (SLE)/Cutaneous Lupus Erythematosus (CLE)	Ph I clinical study: in progress
KK2260	Advanced or metastatic solid tumors	Ph I clinical study: in progress
KK2269	Advanced or metastatic solid tumors	Ph I clinical study: in progress
KK2845	Acute Myeloid Leukemia (AML)	Ph I clinical study: preparation underway
KK8123	X-linked Hypophosphatemia (XLH)	Ph I clinical study: preparation underway
OTL-203	Mucopolysaccharidosis type IH (Hurler syndrome)	Pivotal study (Equivalent to Ph III study): in progress
OTL-201	Mucopolysaccharidosis type IIIA (Sanfilippo syndrome type A)	PoC study (Equivalent to Ph I/II study) : in progress

・ Rocatinlimab is a T cell rebalancing monoclonal antibody that inhibits and reduces pathogenic T cells by targeting the OX40 receptor. The initial antibody was discovered in collaboration between research team of Kyowa Kirin in United States and La Jolla Institute for Immunology. On June 1, 2021, Kyowa Kirin and Amgen entered into an agreement to jointly develop and commercialize rocatinlimab. Under the terms of the agreement, Amgen will lead the development, manufacturing, and commercialization for rocatinlimab for all markets globally, except Japan, where Kyowa Kirin will retain all rights. If approved, the companies will co-promote the asset in the United States and Kyowa Kirin has opt-in rights to co-promote in certain other markets including Europe and Asia. Phase III clinical studies evaluating rocatinlimab in moderate to severe atopic dermatitis (ROCKET Program) is composed of eight studies enrolling adult and adolescent patients. To date, over 3,200 patients have been enrolled in the ROCKET Program with six studies having completed enrollment. In September, Kyowa Kirin announced that HORIZON, which is the first of phase III trials in the ROCKET Program, met its co-primary endpoint and all key secondary

endpoints. Moreover, a Phase II clinical study in moderate to severe asthma was started in May 2024. A Phase III clinical study in prurigo nodularis was started in July 2024.

- Tivozanib, the active ingredient of KHK4951 is a small-molecule vascular endothelial growth factor receptor (VEGFR) -1, -2, and -3 tyrosine kinase inhibitor (TKI) discovered and developed by Kyowa Kirin. KHK4951 is a novel nano-crystalized tivozanib eye drops designed to deliver it efficiently to the posterior ocular tissues and has the potential to provide a novel non-invasive treatment option for patients with neovascular age-related macular degeneration (nAMD) and diabetic macular edema (DME). Phase II clinical studies have been conducted.

- KK4277 is an optimized antibody based on antibodies licensed from SBI Biotech. It has been enhanced with antibody-dependent cell-mediated cytotoxicity (ADCC) activity using our POTELLIGENT technology. Phase I clinical study for the treatment of systemic lupus erythematosus and cutaneous lupus erythematosus has been conducted.

- KK2260 is an EGFR-TfR1 bispecific antibody developed using the Company's proprietary bispecific antibody technology REGULGENT. It is designed as an antibody that achieves selective iron depletion in cancer cells, and in non-clinical trials it showed high efficacy and tolerability. Phase I clinical trial is ongoing.

- KK2269 is an EpCAM-CD40 bispecific antibody developed using the Company's proprietary bispecific antibody technology REGULGENT. It is designed as an antibody that activates only antigen-presenting cells near the tumor by cross-linking EpCAM, which is highly expressed in various tumors, with CD40 on antigen-presenting cells. In non-clinical trials, it was found to exhibit the therapeutic effects of anti-tumor immunity while suppressing systemic side effects. Phase I clinical trial is ongoing.

- KK2845 is the Company's first development product of antibody-drug conjugate (ADC). The target molecule is TIM-3, and the Company is currently preparing for Phase I clinical trial targeting acute myeloid leukemia.

- KK8123 is a potential new treatment for X-linked Hypophosphatemia (XLH) patients which is a human antibody targeting FGF23 in preparation of Phase I study for XLH.

- OTL-203 is an investigational HSC gene therapy in development for the treatment of mucopolysaccharidosis type IH (Hurler syndrome). Orchard Therapeutics is currently implementing a pivotal study (equivalent to a Phase III clinical study) of OTL-203 as a therapy to potentially correct the underlying cause of Hurler syndrome.

- OTL-201 is an investigational HSC gene therapy in development for the treatment of mucopolysaccharidosis type IIIA (Sanfilippo syndrome). A proof-of-concept (Equivalent to Phase I / II study) is ongoing.

R&D pipeline

small molecule large molecule antibody HSC-GT Updated since Dec. 31, 2023 ✓ Updated since Jun. 30, 2024

As of Sep. 30, 2024

Code Name Generic Name Formulation	Mechanizm of Action	Indication	Stage PhI / PhII / PhIII	[In-House or Licensed] Remarks
KK8123 Injection	Anti-FGF23 Fully Human Antibody	X-linked Hypophosphatemia	PhI	[In-House] Preparation underway for PhI as a global product
KK2845	Anti-TIM-3 ADC	Acute Myelogenous Leukemia	PhI	[In-House] Antibody-Drug Conjugate Preparation underway for PhI in Japan as a global product
OTL-203	Hematopoietic Stem Cell (HSC) Gene Therapy	MPS-IH (Hurler Syndrome)	PhI / PhII / PhIII	[In-House] Rare Pediatric Disease (RPD) and Fast Track designations (FDA) Priority Medicines (PRIME) designation (EMA) Area of clinical study: NA and EU
OTL-201	Hematopoietic Stem Cell (HSC) Gene Therapy	MPS-IIIA (Sanfilippo Syndrome type A)	PhI / PhII (Ph Ⅰ/Ph Ⅱ)	[In-House] Rare Pediatric Disease (RPD) designation (FDA) Preparation underway for registrational study (equivalent to PhⅢ study)
KHK4083/AMG 451 rocatinlimab Injection	Anti-OX40 Antibody	Moderate to Severe Atopic Dermatitis	PhI / PhII / PhIII	[In-House] POTELLIGENT Human monoclonal antibody production technology Collaboration agreement with Amgen for the development of rocatinlimab in all the countries except for Japan. Clinical study is being conducted in JP, NA, EU, UK, Middle East, Asia, Oceania, and other regions as a global product
		Prurigo Nodularis	PhI / PhII / ✓	Clinical study is being conducted in JP, NA, EU, Asia, and Oceania as a global product
		Moderate to Severe Asthma	PhI / PhII	Clinical study is being conducted in JP, NA, EU, Asia, and Oceania as a global product
KHK4951 tivozanib Ophthalmic	VEGF Receptor Tyrosine Kinase Inhibitor	Diabetic Macular Edema	PhI / PhII	[In-House] Clinical sudy is being conducted in JP, NA, Asia, and Oceania as a global product
		Neovascular Age-Related Macular Degeneration	PhI / PhII	Clinical sudy is being conducted in JP, NA, Asia, and Oceania as a global product
KK2260 Injection	EGFR-TfR1Bispecific Antibody	Advanced or Metastatic Solid Tumors	PhI	[In-House] REGULGENT Fully human antibody production technology Clinical sudy is being conducted in JP, and a clinical study is prepared under way for PhI in NA as a global product.
KK2269 Injection	EpCAM-CD40Bispecific Antibody	Advanced or Metastatic Solid Tumors	PhI	[In-House] REGULGENT Fully human antibody production technology Clinical sudy is being conducted in JP and NA as a global product
AMG531 romiplostim Injection	Thrombopoietin Receptor Agonist	Aplastic Anemia Previously Untreated with Immunosuppressive Therapy	PhI / PhII / PhIII (Ph Ⅱ/Ph Ⅲ)	[Amgen K-A] product name in Japan: Romiplate Area of clinical study: Asia
KK4277 Injection	Anti-PTPRS Humanized Antibody	Systemic Lupus Erythematosus/Cutaneous Lupus Erythematosus	PhI	[SBI Biotech] POTELLIGENT Clinical sudy is being conducted in JP and Asia

Major Applications and Approvals

Code Name, Generic Name, Product Name	Indication	Application/ Under Review	Countries/ Regions Received Approval in 2024
KRN125(pegfilgrastim, Product name in Japan:G-LASTA)	Mobilization of Hematopoietic Stem Cells into Peripheral Blood for Autologous Blood Stem Cell Transplantation	—	JP
OTL-200(atidarsagene autotemcel, Product name in Europe/US：Libmeldy/Lenmeldy)	Metachromatic Leukodystrophy	—	US
"KHK4827(brodalumab, Product name in Japan and Asia: Lumicef)"	Systemic Sclerosis	JP	—
	Palmoplantar Pustulosis	TW	—
KHK7580(evocalcet, Product name in Japan: Orkedia)	Secondary Hyperparathyroidism	—	CN, TW
AMG531(romiplostim, Product name in Japan: Romiplate)	Aplastic Anemia	TW	—
	Severe Aplastic Anemia	—	KR

Note: Our main progress from September 30, 2024 is as follows.

- In October 2024, we withdrew an application for partial change of approved indication of KHK4827(brodalumab, Product name in Japan and Asia: Lumicef) for systemic sclerosis in Japan.

(5) Summary of Consolidated Earnings Forecasts and Other Forward-looking Statements

No revisions have been made to the consolidated earnings forecasts announced on August 1, 2024.

2. Condensed Quarterly Consolidated Financial Statements and Significant Notes Thereto

(1) Condensed Quarterly Consolidated Statement of Financial Position

(Millions of yen)

	As of December 31, 2023	As of September 30, 2024
Assets		
Non-current assets		
Property, plant and equipment	94,508	102,900
Goodwill	140,450	175,719
Intangible assets	62,918	109,517
Investments accounted for using equity method	12,357	3,379
Other financial assets	33,374	33,527
Retirement benefit asset	15,655	16,056
Deferred tax assets	49,538	44,684
Other non-current assets	6,018	7,444
Total non-current assets	414,818	493,227
Current assets		
Inventories	71,363	73,044
Trade and other receivables	119,082	140,818
Other financial assets	1,923	6,044
Other current assets	15,673	29,673
Cash and cash equivalents	403,083	296,333
Subtotal	611,124	545,911
Assets held for sale	–	2,828
Total current assets	611,124	548,739
Total assets	1,025,942	1,041,966

(1) Condensed Quarterly Consolidated Statement of Financial Position (continued)

(Millions of yen)

	As of December 31, 2023	As of September 30, 2024
Equity		
Share capital	26,745	26,745
Capital surplus	464,731	464,664
Treasury shares	(2,933)	(39,272)
Retained earnings	338,764	363,898
Other components of equity	9,112	19,214
Total equity attributable to owners of parent	836,418	835,248
Total equity	836,418	835,248
Liabilities		
Non-current liabilities		
Liabilities from application of equity method	13,966	12,004
Retirement benefit liability	293	407
Provisions	8,439	8,540
Deferred tax liabilities	428	454
Other financial liabilities	16,111	18,851
Other non-current liabilities	17,049	10,778
Total non-current liabilities	56,287	51,035
Current liabilities		
Trade and other payables	92,983	108,972
Provisions	2,379	2,965
Other financial liabilities	8,136	4,855
Income taxes payable	4,022	9,807
Other current liabilities	25,718	29,084
Total current liabilities	133,237	155,683
Total liabilities	189,524	206,718
Total equity and liabilities	1,025,942	1,041,966

(2) Condensed Quarterly Consolidated Statement of Profit or Loss and Condensed Quarterly Consolidated Statement of Comprehensive Income

Condensed Quarterly Consolidated Statement of Profit or Loss

(Millions of yen)

	January 1, 2023 to September 30, 2023	January 1, 2024 to September 30, 2024
Revenue	306,053	362,798
Cost of sales	(76,974)	(94,006)
Gross profit	229,079	268,792
Selling, general and administrative expenses	(119,317)	(123,617)
Research and development expenses	(51,174)	(74,293)
Share of profit (loss) of investments accounted for using equity method	2,285	3,534
Other income	16,574	13,264
Other expenses	(16,620)	(16,880)
Finance income	3,650	2,669
Finance costs	(138)	(1,896)
Profit before tax	64,339	71,573
Income tax expense	(10,785)	(15,672)
Profit	53,554	55,901
Profit attributable to		
Owners of parent	53,554	55,901
Earnings per share		
Basic earnings per share (Yen)	99.62	105.20
Diluted earnings per share (Yen)	99.61	105.19

Condensed Quarterly Consolidated Statement of Comprehensive Income

(Millions of yen)

	January 1, 2023 to September 30, 2023	January 1, 2024 to September 30, 2024
Profit	53,554	55,901
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	750	334
Remeasurements of defined benefit plans	–	127
Total of items that will not be reclassified to profit or loss	750	461
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	23,575	7,913
Cash flow hedges	–	1,798
Share of other comprehensive income of investments accounted for using equity method	84	96
Total of items that may be reclassified to profit or loss	23,659	9,808
Other comprehensive income	24,409	10,269
Comprehensive income	77,963	66,170
Comprehensive income attributable to		
Owners of parent	77,963	66,170

(3) Condensed Quarterly Consolidated Statement of Changes in Equity

January 1, 2023 to September 30, 2023

(Millions of yen)

	Equity attributable to owners of parent					
					Other components of equity	
	Share capital	Capital surplus	Treasury shares	Retained earnings	Share acquisition rights	Exchange differences on translation of foreign operations
Balance at January 1, 2023	26,745	464,434	(3,177)	285,842	219	(12,247)
Profit	–	–	–	53,554	–	–
Other comprehensive income	–	–	–	–	–	23,659
Total comprehensive income	–	–	–	53,554	–	23,659
Dividends of surplus	–	–	–	(29,027)	–	–
Purchase of treasury shares	–	–	(8)	–	–	–
Disposal of treasury shares	–	37	79	–	–	–
Share-based remuneration transactions	–	237	152	–	(116)	–
Transfer from other components of equity to retained earnings	–	–	–	182	–	–
Total transactions with owners	–	274	223	(28,845)	(116)	–
Balance at September 30, 2023	26,745	464,708	(2,954)	310,551	103	11,412

	Equity attributable to owners of parent					Total equity
	Other components of equity				Total	
	Financial assets measured at fair value through other comprehensive income	Remeasure-ments of defined benefit plans	Cash flow hedges	Total		
Balance at January 1, 2023	1,010	–	–	(11,018)	762,826	762,826
Profit	–	–	–	–	53,554	53,554
Other comprehensive income	750	–	–	24,409	24,409	24,409
Total comprehensive income	750	–	–	24,409	77,963	77,963
Dividends of surplus	–	–	–	–	(29,027)	(29,027)
Purchase of treasury shares	–	–	–	–	(8)	(8)
Disposal of treasury shares	–	–	–	–	116	116
Share-based remuneration transactions	–	–	–	(116)	274	274
Transfer from other components of equity to retained earnings	(182)	–	–	(182)	–	–
Total transactions with owners	(182)	–	–	(298)	(28,646)	(28,646)
Balance at September 30, 2023	1,578	–	–	13,093	812,143	812,143

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

January 1, 2024 to September 30, 2024

(Millions of yen)

	Equity attributable to owners of parent					
					Other components of equity	
	Share capital	Capital surplus	Treasury shares	Retained earnings	Share acquisition rights	Exchange differences on translation of foreign operations
Balance at January 1, 2024	26,745	464,731	(2,933)	338,764	102	8,823
Profit	–	–	–	55,901	–	–
Other comprehensive income	–	–	–	–	–	8,010
Total comprehensive income	–	–	–	55,901	–	8,010
Dividends of surplus	–	–	–	(30,895)	–	–
Purchase of treasury shares	–	–	(36,418)	–	–	–
Disposal of treasury shares	–	(135)	68	–	–	–
Share-based remuneration transactions	–	68	11	–	(40)	–
Transfer from other components of equity to retained earnings	–	–	–	127	–	–
Total transactions with owners	–	(67)	(36,339)	(30,767)	(40)	–
Balance at September 30, 2024	26,745	464,664	(39,272)	363,898	63	16,833

	Equity attributable to owners of parent					Total equity
	Other components of equity				Total	
	Financial assets measured at fair value through other comprehensive income	Remeasure-ments of defined benefit plans	Cash flow hedges	Total		
Balance at January 1, 2024	1,984	–	(1,798)	9,112	836,418	836,418
Profit	–	–	–	–	55,901	55,901
Other comprehensive income	334	127	1,798	10,269	10,269	10,269
Total comprehensive income	334	127	1,798	10,269	66,170	66,170
Dividends of surplus	–	–	–	–	(30,895)	(30,895)
Purchase of treasury shares	–	–	–	–	(36,418)	(36,418)
Disposal of treasury shares	–	–	–	–	(67)	(67)
Share-based remuneration transactions	–	–	–	(40)	39	39
Transfer from other components of equity to retained earnings	–	(127)	–	(127)	–	–
Total transactions with owners	–	(127)	–	(167)	(67,340)	(67,340)
Balance at September 30, 2024	2,318	–	–	19,214	835,248	835,248

(4) Condensed Quarterly Consolidated Statement of Cash Flows

(Millions of yen)

	January 1, 2023 to September 30, 2023	January 1, 2024 to September 30, 2024
Cash flows from operating activities		
Profit before tax	64,339	71,573
Depreciation and amortization	15,451	18,798
Impairment losses (reversal of impairment losses)	9,326	1,535
Increase (decrease) in provisions	2,101	622
Share of loss (profit) of investments accounted for using equity method	(2,285)	(3,534)
Gain on sales of share and valuation of remaining share (gain)	(14,799)	(7,840)
Foreign exchange loss (gain)	11,991	7,288
Decrease (increase) in inventories	(3,186)	(1,784)
Decrease (increase) in trade receivables	4,897	(15,696)
Increase (decrease) in trade payables	715	(3,418)
Increase (decrease) in contract liabilities	(6,090)	(7,892)
Income taxes paid	(5,653)	(12,322)
Other	7,479	22,262
Net cash provided by (used in) operating activities	84,286	69,592
Cash flows from investing activities		
Purchase of property, plant and equipment	(13,006)	(18,648)
Proceeds from sale of property, plant and equipment	180	3,374
Purchase of intangible assets	(9,355)	(25,631)
Purchase of shares of subsidiaries resulting in change in scope of consolidation	–	(48,196)
Proceeds from sale of investments in subsidiaries resulting in change in scope of consolidation	7,780	–
Payments for sale of investments in subsidiaries resulting in change in scope of consolidation	–	(5,603)
Proceeds from redemption of bonds of subsidiaries and associates	2,000	–
Other	(94)	(1,117)
Net cash provided by (used in) investing activities	(12,495)	(95,821)
Cash flows from financing activities		
Redemption of bonds with share acquisition rights	–	(9,621)
Repayments of lease liabilities	(2,625)	(2,984)
Purchase of treasury shares	(8)	(36,418)
Decrease (increase) in deposits for the purchase of treasury shares	–	(3,590)
Dividends paid	(29,027)	(30,895)
Other	262	(163)
Net cash provided by (used in) financing activities	(31,397)	(83,670)
Effect of exchange rate changes on cash and cash equivalents	2,678	3,149
Net increase (decrease) in cash and cash equivalents	43,072	(106,750)

	January 1, 2023 to September 30, 2023	January 1, 2024 to September 30, 2024
Cash and cash equivalents at beginning of period	339,194	403,083
Cash and cash equivalents at end of period	382,266	296,333

(5) Notes to Condensed Quarterly Consolidated Financial Statements

Segment information

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

Notes on going concern assumption

No applicable items.

Changes in presentation

Condensed Quarterly Consolidated Statement of Cash Flows

"Proceeds from sale of property, plant and equipment," which had previously been included in "Other" of "Cash flows from investing activities" in the nine months ended September 30, 2023, has been presented separately because its monetary materiality has increased. To reflect this change in the presentation method, the Group has reclassified the amount in its Condensed Quarterly Consolidated Financial Statements for the nine months ended September 30, 2023.
As a result, ¥86 million presented as "Other" in "Cash flows from investing activities" in the Condensed Quarterly Consolidated Statement of Cash Flows for the nine months ended September 30, 2023, was reclassified as "Proceeds from sale of property, plant and equipment" of ¥180 million and "Other" of negative ¥94 million.

Cash flow information

The ¥9,621 million in redemption of bonds with share acquisition rights during the nine months ended September 30, 2024 is an expenditure related to bonds with share acquisition rights issued by Orchard Therapeutics plc before the business combination.
The ¥5,603 million in payments for sale of investments in subsidiaries resulting in change in scope of consolidation during the nine months ended September 30, 2024 is the difference between the ¥2,042 million in upfront payment received as consideration for the transfer and the ¥7,644 million in cash and cash equivalents held by Kyowa Kirin China Pharmaceutical Co., Ltd. immediately before the sale.