

Quarterly Securities Report

(The third quarter of 147th Business Term)
for The Nine-month Period and Three-month
Quarter Ended December 31, 2023

TAKEDA PHARMACEUTICAL COMPANY LIMITED
AND ITS SUBSIDIARIES

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A. Company Information

I. Overview of Takeda

1. Key Consolidated Financial Data

Term	JPY (millions), unless otherwise indicated		
	Nine-month period ended December 31,	Nine-month period ended December 31,	For the year ended March 31,
	2022	2023	2023
Revenue	3,071,322	3,212,893	4,027,478
<Three-month period ended December 31>	1,096,551	1,111,186	
Profit before tax	327,175	100,313	375,090
Net profit for the period	285,903	147,191	317,038
Net profit (loss) attributable to owners of the Company	285,883	147,085	317,017
<Three-month period ended December 31>	119,127	105,720	
Total comprehensive income for the period	750,209	625,154	911,574
Total equity	6,176,498	6,742,607	6,354,672
Total assets	13,504,705	14,222,947	13,957,750
Basic earnings (loss) per share (JPY)	184.32	94.10	204.29
<Three-month period ended December 31>	76.63	67.38	
Diluted earnings per share (JPY)	182.65	93.17	201.94
Ratio of equity attributable to owners of the Company to total assets (%)	45.7	47.4	45.5
Net cash from operating activities	683,463	437,756	977,156
Net cash used in investing activities	(168,610)	(402,378)	(607,102)
Net cash used in financing activities	(702,548)	(296,193)	(709,148)
Cash and cash equivalents at the end of the period	685,141	288,359	533,530

(Note 1) All amounts shown are rounded to the nearest million JPY.

(Note 2) The key consolidated financial data for the nine-month period ended December 31, 2022 and 2023 are based on the condensed interim consolidated financial statements prepared in accordance with IAS 34.

2. Business Overview

There has been no significant change in our business for the nine-month period ended December 31, 2023.

As of December 31, 2023, Takeda consisted of 190 entities comprised of 172 consolidated subsidiaries (including partnerships), 17 associates accounted for using the equity method, and Takeda Pharmaceutical Company Limited. There has been no significant change in our group companies for the nine-month period ended December 31, 2023.

II. Operating and Financial Review

1. Risk Factors

There were no new risk factors identified for the nine-month period ended December 31, 2023 as well as no significant changes in the risk factors compared to what we reported in our Annual Securities Report for the year ended March 31, 2023 which was filed in Japan.

2. Analysis on Business Performance, Financial Position and Cash Flows

(1) Consolidated Financial Results (April 1 to December 31, 2023)

	Billion JPY or percentage				
	FY2022 Q3YTD	FY2023 Q3YTD	Change versus the same period of the previous fiscal year		
			AER		CER
			Amount of Change	% Change	% Change
Revenue	3,071.3	3,212.9	141.6	4.6 %	0.0 %
Cost of sales	(934.3)	(1,044.2)	(109.9)	11.8 %	6.8 %
Selling, general and administrative expenses	(742.5)	(768.6)	(26.1)	3.5 %	(1.3)%
Research and development expenses	(472.4)	(534.1)	(61.7)	13.1 %	7.3 %
Amortization and impairment losses on intangible assets associated with products	(409.2)	(507.0)	(97.8)	23.9 %	16.3 %
Other operating income	16.7	10.8	(5.9)	(35.4)%	(35.7)%
Other operating expenses	(127.6)	(145.7)	(18.0)	14.1 %	9.1 %
Operating profit	401.9	224.1	(177.8)	(44.2)%	(42.9)%
Finance income and (expenses), net	(71.6)	(126.6)	(54.9)	76.7 %	77.9 %
Share of profit (loss) of investments accounted for using the equity method	(3.1)	2.7	5.9	—	—
Profit before tax	327.2	100.3	(226.9)	(69.3)%	(67.9)%
Income tax (expenses) benefit	(41.3)	46.9	88.2	—	—
Net profit for the period	285.9	147.2	(138.7)	(48.5)%	(50.1)%

In this section, when comparing results to the same period of the previous fiscal year, the amount of change and percentage change based on Actual Exchange Rates are presented in “AER” (which is presented in accordance with IFRS) and percentage change based on Constant Exchange Rate (which is a non-IFRS measure) is presented in “CER”. Please refer to Core Results (April 1 to December 31, 2023), Definition of Core financial measures and Constant Exchange Rate change, for the definition of “Constant Exchange Rate change”.

Revenue

Revenue for the nine-month period ended December 31, 2023 was JPY 3,212.9 billion (JPY +141.6 billion and +4.6% AER, +0.0% CER). The increase is attributable to favorable foreign exchange rates and growth from business momentum of Plasma-Derived Therapies (“PDT”) Immunology, Gastroenterology (“GI”) and Rare Diseases. The increase of these business areas was offset by the decrease in Oncology and Neuroscience. Although the decrease was partially mitigated by favorable foreign exchange rates, it was largely impacted by generic erosion and intensified competition on certain products in the current period. In addition, revenue outside of our five key business areas decreased mainly due to lower revenue contribution from COVID-19 vaccines in Japan.

Revenue by Geographic Region

The following shows revenue by geographic region:

Revenue:	FY2022 Q3YTD	FY2023 Q3YTD	Billion JPY or percentage		
			Change versus the same period of the previous fiscal year		
			AER		CER
			Amount of Change	% Change	% Change
Japan	389.8	342.6	(47.2)	(12.1)%	(12.3)%
United States	1,621.8	1,685.5	63.7	3.9 %	(1.8)%
Europe and Canada	632.4	721.5	89.1	14.1 %	4.7 %
Asia (excluding Japan)	169.0	188.8	19.8	11.7 %	8.9 %
Latin America	121.4	138.4	16.9	14.0 %	15.2 %
Russia/CIS	66.7	45.4	(21.3)	(32.0)%	(16.9)%
Other* ¹	70.2	90.7	20.5	29.3 %	35.4 %
Total	3,071.3	3,212.9	141.6	4.6 %	0.0 %

*1 Other includes the Middle East, Oceania and Africa.

Revenue by Business Area

The following shows revenue by business area:

Revenue:	FY2022 Q3YTD	FY2023 Q3YTD	Billion JPY or percentage		
			Change versus the same period of the previous fiscal year		
			AER		CER
			Amount of Change	% Change	% Change
GI	857.5	936.1	78.5	9.2 %	3.6 %
Rare Diseases	553.6	585.1	31.5	5.7 %	3.3 %
Rare Hematology	232.6	230.0	(2.6)	(1.1)%	(4.3)%
Rare Genetics and Other	321.0	355.0	34.1	10.6 %	8.9 %
PDT Immunology	502.4	611.2	108.8	21.7 %	16.2 %
Oncology	345.0	346.3	1.3	0.4 %	(2.2)%
Neuroscience	477.1	474.9	(2.3)	(0.5)%	(5.8)%
Other	335.7	259.4	(76.3)	(22.7)%	(28.3)%
Total	3,071.3	3,212.9	141.6	4.6 %	0.0 %

Year-on-year change in revenue for this nine-month period in each of our business areas was primarily attributable to the following products:

GI

In GI, revenue was JPY 936.1 billion (JPY +78.5 billion and +9.2% AER, +3.6% CER).

Sales of ENTYVIO (for ulcerative colitis (“UC”) and Crohn’s disease (“CD”)) were JPY 619.3 billion (JPY +71.4 billion and +13.0% AER, +6.6% CER). Sales in the U.S. were JPY 431.8 billion (JPY +43.5 billion and +11.2% AER). The increase was due to favorable foreign exchange rates and demand in the first line biologic inflammatory bowel disease (“IBD”) population primarily in UC. Sales in Europe and Canada were JPY 143.1 billion (JPY +20.7 billion and +16.9% AER). The increase was primarily due to favorable foreign exchange rates and new patient gains by an increased use of the subcutaneous formulation.

Sales of GATTEX/REVESTIVE (for short bowel syndrome) were JPY 90.0 billion (JPY +11.8 billion and +15.1% AER, +10.9% CER). The increase was primarily due to increased demand in the U.S., Europe and Japan, expansion activities (infant indication label expansion and geographic expansion), and favorable exchange rates.

Sales of TAKECAB/VOCINTI (for acid-related diseases) were JPY 90.3 billion (JPY +5.8 billion and +6.8% AER, +6.2% CER). The increase was primarily due to increased sales in Japan and the Growth and Emerging Markets including Brazil and China.

Sales of DEXILANT (for acid reflux disease) were JPY 36.1 billion (JPY -19.0 billion and -34.5% AER, -38.7% CER). The decrease was due to the loss of exclusivity and the termination of the authorized generics program in the U.S.

Rare Diseases

In Rare Diseases, revenue was JPY 585.1 billion (JPY +31.5 billion and +5.7% AER, +3.3% CER).

Revenue of Rare Hematology was JPY 230.0 billion (JPY -2.6 billion and -1.1% AER, -4.3% CER).

Sales of FEIBA (for hemophilia A and B) were JPY 28.9 billion (JPY -3.7 billion and -11.3% AER, -14.1% CER). The decrease was mainly due to competition in many countries as well as tender delays in Growth and Emerging Markets.

Sales of VONVENDI (for von Willebrand disease) were JPY 12.0 billion (JPY +2.8 billion and +30.6% AER, +22.5% CER). The increase was primarily due to increased demand in the U.S.

Sales of ADVATE (for hemophilia A) were JPY 93.9 billion (JPY +1.8 billion and +2.0% AER, -0.9% CER). The increase was attributable to favorable foreign exchange rates.

The increase of VONVENDI and ADVATE was partially offset by the decrease of other rare hematology products.

Revenue of Rare Genetics and Other was JPY 355.0 billion (JPY +34.1 billion and +10.6% AER, +8.9% CER).

Sales of TAKHZYRO (for hereditary angioedema) were JPY 136.4 billion (JPY +19.5 billion and +16.7% AER, +11.5% CER). The continued growth was attributable to sustained launch momentum, expansion into new patient populations such as pediatrics, rising diagnosis rates, the growth of the prophylactic market, and favorable exchange rates.

Sales of LIVTENCITY (for post-transplant cytomegalovirus (“CMV”) infection/disease) were JPY 13.9 billion (JPY +6.6 billion and +90.8% AER, +78.8% CER). The increase was primarily attributable to strong market penetration and successful launch performance in the U.S., complemented by continued geographical expansion in Europe.

Sales of enzyme replacement therapy ELAPRASE (for Hunter syndrome) were JPY 70.0 billion (JPY +5.0 billion and +7.7% AER, +7.5% CER). The increase was primarily due to strong demand in the Growth and Emerging Markets.

PDT Immunology

In PDT Immunology, revenue was JPY 611.2 billion (JPY +108.8 billion and +21.7% AER, +16.2% CER).

Aggregate sales of immunoglobulin products were JPY 485.7 billion (JPY +95.2 billion and +24.4% AER, +18.4% CER). Sales of each of our three global immunoglobulin brands marked double digit percentage of revenue growth, due to continued strong demand globally and growing supply, as well as favorable foreign exchange rates. Those include GAMMAGARD LIQUID/KIOVIG (for the treatment of primary immunodeficiency (“PID”) and multifocal motor neuropathy (“MMN”)), and subcutaneous immunoglobulin therapies (CUVITRU and HYQVIA) which are growing due to their benefit to patients and convenience in administration compared to intravenous therapies.

Aggregate sales of albumin products including HUMAN ALBUMIN and FLEXBUMIN (both primarily used for hypovolemia and hypoalbuminemia) were JPY 94.3 billion (JPY +8.8 billion and +10.2% AER, +6.9% CER). The increase was primarily driven by strong albumin demand in China.

Oncology

In Oncology, revenue was JPY 346.3 billion (JPY +1.3 billion and +0.4% AER, -2.2% CER).

Sales of VELCADE (for multiple myeloma) were JPY 4.1 billion (JPY -20.6 billion and -83.3% AER, -84.2% CER). The decrease was due to generic erosion in the U.S.

Sales of NINLARO (for multiple myeloma) were JPY 66.7 billion (JPY -9.2 billion and -12.1% AER, -15.1% CER). The decrease was due to intensified competition and decreased demand mainly in the U.S, partially aided by favorable foreign exchange rates.

Sales of ADCETRIS (for malignant lymphomas) were JPY 84.2 billion (JPY +18.5 billion and +28.1% AER, +27.9% CER). The increase was led by strong growth in Growth and Emerging Markets.

Sales of ICLUSIG (for leukemia) were JPY 41.5 billion (JPY +5.9 billion and +16.7% AER, +9.2% CER). The increase was due to steady growth in the U.S. and favorable foreign exchange rates.

Sales of ALUNBRIG (for small-cell lung cancer) were JPY 21.1 billion (JPY +5.4 billion and +34.0% AER, +30.3% CER). The increase benefited from strong demand across all regions.

Sales of other Oncology products in aggregate increased year-on-year, including the contribution from FRUZAQLA (for colorectal cancer), a product newly launched in the U.S. in November 2023.

Neuroscience

In Neuroscience, revenue was JPY 474.9 billion (JPY -2.3 billion and -0.5% AER, -5.8% CER).

Sales of VYVANSE/ELVANSE (for attention deficit hyperactivity disorder (“ADHD”)) were JPY 312.9 billion (JPY -22.6 billion and -6.7% AER, -12.1% CER). The decrease was due to the multiple generic entrants in the U.S. starting from August 2023, while the growth of the adult market in Europe and favorable foreign exchange rates could only offset the negative impacts partially.

Sales of ADDERALL XR (for ADHD) were JPY 35.2 billion (JPY +16.2 billion and +84.7% AER, +73.5% CER). The increase was primarily due to a shortage of generic versions of the instant release formulation marketed by competitors in the U.S.

Sales of INTUNIV (for ADHD) were JPY 25.4 billion (JPY +8.8 billion and +52.7% AER, +50.2% CER). The increase was primarily due to buy-back of full rights in Japan.

The increase of ADDERALL XR and INTUNIV was partially offset by the decrease of other neuroscience products such as ROZEREM (for insomnia), attributable to the continued impact of generic products in Japan.

Cost of Sales

Cost of Sales was JPY 1,044.2 billion (JPY +109.9 billion and +11.8% AER, +6.8% CER). The increase was primarily due to revenue growth in our five key business area with a change in product mix and the depreciation of Japanese yen as compared to the same period of the previous fiscal year. This was partially offset by a decrease in non-cash charges related to the unwind of the fair value step up on acquired inventories recognized in connection with the acquisition of Shire.

Selling, General and Administrative (SG&A) expenses

SG&A expenses were JPY 768.6 billion (JPY +26.1 billion and +3.5% AER, -1.3% CER). The increase was mainly due to the depreciation of Japanese yen partially offset by various cost efficiencies.

Research and Development (R&D) expenses

R&D expenses were JPY 534.1 billion (JPY +61.7 billion and +13.1% AER, +7.3% CER). The increase was mainly due to various investments in pipeline programs and the depreciation of Japanese yen.

Amortization and Impairment Losses on Intangible Assets Associated with Products

Amortization and Impairment Losses on Intangible Assets Associated with Products was JPY 507.0 billion (JPY +97.8 billion and +23.9% AER, +16.3% CER). The increase was mainly due to an increase in impairment charges for certain assets related to in-process R&D and marketed products and an increase of amortization expenses due to the depreciation of Japanese yen. The JPY 119.3 billion impairment losses recorded in the current period primarily includes JPY 74.0 billion impairment charges for ALOFISEL (for complex Crohn's perianal fistulas) following topline results of phase 3 ADMIRE-CD II trial and JPY 28.5 billion impairment charges following a decision to voluntarily withdraw EXKIVITY (for non-small cell lung cancer) globally.

Other Operating Income

Other Operating Income was JPY 10.8 billion (JPY -5.9 billion and -35.4% AER, -35.7% CER).

Other Operating Expenses

Other Operating Expenses were JPY 145.7 billion (JPY +18.0 billion and +14.1% AER, +9.1% CER). The increase was primarily driven by increases of restructuring expenses and additional losses recorded for the supply agreement litigation with AbbVie, Inc. (AbbVie) in the current period, partially offset by a decrease in valuation reserve for pre-launch inventories.

Operating Profit

As a result of the above factors, Operating Profit was JPY 224.1 billion (JPY -177.8 billion and -44.2% AER, -42.9% CER).

Net Finance Expenses

Net Finance Expenses were JPY 126.6 billion (JPY +54.9 billion and +76.7% AER, +77.9% CER). The increase of Net Finance Expenses compared to the same period of the previous fiscal year was primarily due to a decrease in financial income reflecting gains from acquisitions of prior equity method companies and a positive impact from the remeasurement of warrants to purchase stocks of company held by Takeda recorded in the same period of the previous fiscal year.

Share of Profit of Investments Accounted for Using the Equity Method

Share of Profit of Investments Accounted for Using the Equity Method was JPY 2.7 billion (JPY +5.9 billion, compared to Share of Loss of Investments Accounted for Using the Equity Method of JPY 3.1 billion in the same period of the previous fiscal year).

Income Tax (Expenses) Benefit

Income Tax Benefit was JPY 46.9 billion (JPY +88.2 billion, compared to Income Tax Expenses of JPY 41.3 billion in the same period of the previous fiscal year). The increase was primarily due to a tax expense reduction of JPY 63.5 billion resulting from the reversal of the income taxes payable in excess of the settlement with Irish Revenue Commissioners with respect to a tax assessment related to the treatment of an acquisition break fee Shire received from AbbVie in 2014 as well as lower pretax earnings. These increases were partially offset by the tax charges from the write-down of deferred tax assets and legal entity restructuring in the current period.

Net Profit for the Period

Net Profit for the Period was JPY 147.2 billion (JPY -138.7 billion and -48.5% AER, -50.1% CER).

Core Results (April 1 to December 31, 2023)

Definition of Core financial measures and Constant Exchange Rate change

Takeda uses the concept of Core financial measures for measuring financial performance. These measures are not defined by International Financial Reporting Standards (IFRS).

Core Revenue represents revenue adjusted to exclude significant items unrelated to Takeda's core operations.

Core Operating Profit represents net profit adjusted to exclude income tax expenses, the share of profit or loss of investments accounted for using the equity method, finance expenses and income, other operating expenses and income, amortization and impairment losses on acquired intangible assets and other items unrelated to Takeda's core operations, such as non-recurring items, purchase accounting effects and transaction related costs.

Core EPS represents net profit adjusted to exclude the impact of items excluded in the calculation of Core Operating Profit, and other non-operating items (e.g. amongst other items, fair value adjustments and the imputed financial charge related to contingent consideration) that are unusual, non-recurring in nature or unrelated to Takeda's ongoing operations and the tax effect of each of the adjustments, divided by the average outstanding shares (excluding treasury shares) of the reporting periods presented.

Constant Exchange Rate (CER) change eliminates the effect of foreign exchange rates from year-over-year comparisons by translating Reported or Core results for the current period using corresponding exchange rates in the same period of the previous fiscal year.

Results of Core Operations

	Billion JPY or percentage				
	FY2022 Q3YTD	FY2023 Q3YTD	Change versus the same period of the previous fiscal year		
			AER		CER
			Amount of Change	% change	% change
Core Revenue	3,071.3	3,212.9	141.6	4.6 %	0.0 %
Core Operating Profit	954.7	865.6	(89.1)	(9.3)%	(12.7)%
Core EPS (JPY)	456	412	(44)	(9.7)%	(12.9)%

Core Revenue

Core Revenue for the nine-month period ended December 31, 2023 was JPY 3,212.9 billion (JPY +141.6 billion and +4.6% AER, +0.0% CER). There were no significant items unrelated to Takeda's core operations excluded from revenue in the current period or in the same period of the previous fiscal year, and, accordingly, Core Revenue for these periods is the same as Reported Revenue. Business momentum was led by Takeda's Growth and Launch Products* which totaled JPY 1,384.7 billion (JPY +216.6 billion and +18.5% AER, +12.7% CER).

* Takeda's Growth and Launch Products

GI: ENTYVIO, ALOFISEL

Rare Diseases: TAKHZYRO, LIVTENCITY, ADZYNMA

PDT Immunology: Immunoglobulin products including GAMMAGARD LIQUID/KIOVIG, HYQVIA, and CUVITRU,

Albumin products including HUMAN ALBUMIN and FLEXBUMIN

Oncology: ALUNBRIG, EXKIVITY (Takeda decided to voluntarily withdraw the product globally), FRUZAQLA

Other: QDENGGA

Core Operating Profit

Core Operating Profit for the current period was JPY 865.6 billion (JPY -89.1 billion and -9.3% AER, -12.7% CER). The decrease was primarily due to a change in product mix and investments in various pipeline programs and data and technology.

Core EPS

Core EPS for the current period was JPY 412 (JPY -44 and -9.7% AER, -12.9% CER).

(2) Consolidated Financial Position

The amount of change from the previous fiscal year-end is presented based on Actual Exchange Rates.

Assets.

Total Assets as of December 31, 2023 were JPY 14,222.9 billion (JPY +265.2 billion). The increases of Goodwill, Inventories, and Property, Plant and Equipment (JPY +320.6 billion, JPY +183.2 billion, JPY +150.3 billion, respectively) were mainly due to the effect of foreign currency translation. These increases were partially offset by a decrease in Cash and Cash Equivalents (JPY -245.2 billion). In addition, Intangible Assets decreased (JPY -172.6 billion) mainly due to amortization along with impairments partially offset by the effect of foreign currency translation.

Liabilities.

Total Liabilities as of December 31, 2023 were JPY 7,480.3 billion (JPY -122.7 billion). The decrease of Trade and Other Payables (JPY -165.6 billion) was primarily due to payments for the remaining upfront payment related to the acquisition of TAK-279 from Nimbus Therapeutics, LLC (Nimbus) and the exclusive license agreement with HUTCHMED (China) Limited (HUTCHMED). The decrease of Income Taxes Payable (JPY -140.4 billion) was mainly due to income taxes paid during the current period. In addition, Deferred Tax Liabilities decreased (JPY -137.6 billion). These decreases were partially offset by an increase in Bonds and Loans (JPY +281.8 billion) due to the issuance of commercial paper and the effect of foreign currency translation. Total Bonds and Loans were JPY 4,664.2 billion*.

* The carrying amount of Bonds was JPY 3,927.6 billion and Loans was JPY 736.5 billion as of December 31, 2023. Breakdown of Bonds and Loans' carrying amount is as follows.

Bonds:

Name of Bond (Face Value if Denominated in Foreign Currency)	Issuance	Maturity	Carrying Amount (Billion JPY)
Unsecured US dollar denominated senior notes (USD 1,301 million)	June 2015	June 2025 ~ June 2045	185.5
Unsecured US dollar denominated senior notes (USD 3,000 million)	September 2016	September 2026	410.6
Unsecured Euro denominated senior notes (EUR 3,000 million)	November 2018	November 2026 ~ November 2030	467.9
Unsecured US dollar denominated senior notes (USD 1,750 million)	November 2018	November 2028	246.9
Hybrid bonds (subordinated bonds)	June 2019	June 2079	499.4
Unsecured US dollar denominated senior notes (USD 7,000 million)	July 2020	March 2030 ~ July 2060	986.9
Unsecured Euro denominated senior notes (EUR 3,600 million)	July 2020	July 2027 ~ July 2040	560.8
Unsecured JPY denominated senior bonds	October 2021	October 2031	249.5
Commercial paper	November 2023 ~ December 2023	February 2024 ~ March 2024	320.0
Total			3,927.6

Loans:

Name of Loan (Face Value if Denominated in Foreign Currency)	Execution	Maturity	Carrying Amount (Billion JPY)
Syndicated loans	April 2016	April 2026	100.0
Syndicated loans	April 2017	April 2027	113.5
Syndicated loans (USD 1,500 million)	April 2017	April 2027	212.6
Syndicated loans	April 2023	April 2030	100.0
Bilateral loans	March 2016 ~ March 2023	April 2024 ~ March 2029	210.0
Other			0.4
Total			736.5

On April 26, 2023, Takeda repaid JPY 100.0 billion in Syndicated Loans falling due and on the same day entered into new Syndicated Loans of JPY 100.0 billion maturing on April 26, 2030. Following this, Takeda redeemed USD 1,000 million of unsecured senior notes issued in September 2016 on their maturity date of September 23, 2023. Furthermore, Takeda redeemed USD 500 million of unsecured senior notes issued in November 2018 on their maturity date of November 26, 2023. Takeda had short term commercial paper drawings outstanding of JPY 320.0 billion as at December 31, 2023.

Equity.

Total Equity as of December 31, 2023 was JPY 6,742.6 billion (JPY +387.9 billion). The increase of Other Components of Equity (JPY +481.5 billion) was mainly due to fluctuation in currency translation adjustments reflecting the depreciation of Japanese yen. This increase was partially offset by a decrease in Retained Earnings (JPY -144.3 billion) mainly due to the decrease of JPY 287.8 billion related to dividends payments while Net Profit for the Period contributed to an increase.

Consolidated Cash Flows

	Billion JPY	
	FY2022 Q3YTD	FY2023 Q3YTD
Net cash from (used in) operating activities	683.5	437.8
Net cash from (used in) investing activities	(168.6)	(402.4)
Net cash from (used in) financing activities	(702.5)	(296.2)
Net increase (decrease) in cash and cash equivalents	(187.7)	(260.8)
Cash and cash equivalents at the beginning of the year	849.7	533.5
Effects of exchange rate changes on cash and cash equivalents	23.1	15.6
Cash and cash equivalents at the end of the period	685.1	288.4

The amount of change from the same period of the previous fiscal year is presented based on Actual Exchange Rates.

Net cash from operating activities

Net cash from operating activities for the current period was JPY 437.8 billion (JPY -245.7 billion). The decrease was due to unfavorable impacts from Changes in Assets and Liabilities, unfavorable impacts from a lower net profit for the period adjusted for non-cash items and other adjustments, and other changes.

Net cash used in investing activities

Net cash used in investing activities was JPY 402.4 billion (JPY +233.8 billion). This increase was mainly due to an increase in Acquisition of Intangible Assets related to the acquisition of TAK-279 from Nimbus and the exclusive license agreement with HUTCHMED.

Net cash used in financing activities

Net cash used in financing activities was JPY 296.2 billion (JPY -406.4 billion). The decrease was mainly due to a net increase in commercial paper drawings of JPY 280.0 billion, a net decrease in redemption of bonds of JPY 60.9 billion, and the settlement of cross currency interest rate swaps related to bonds during the current period.

(3) Research & Development Activities and Results

Research and development expenses for the nine-month period ended December 31, 2023 were JPY 534.1 billion.

Takeda's R&D engine is focused on translating science into highly innovative, life-transformative medicines that make a critical difference to patients. Takeda supports dedicated R&D efforts across three areas: Innovative Biopharma, Plasma-Derived Therapies ("PDT") and Vaccines. The R&D engine for Innovative Biopharma is the largest component of our R&D investment and has produced exciting new molecular entities ("NMEs") that represent potential best-in-class and/or first-in-class medicines in areas of high unmet medical need across our core therapeutic areas (Gastrointestinal and inflammation, neuroscience, oncology, and rare genetics and hematology). We are working to harness the potential of cell and gene therapies by investing in new capabilities and next-generation platforms internally and through a network of partnerships. We are embracing data and digital technologies to improve the quality of innovation and accelerate execution.

Takeda's pipeline is positioned to support both the near-term and mid- to long-term sustained growth of the company. Once first approval of a product is achieved, Takeda R&D is equipped to support geographic expansions of such approval and approvals in additional indications, as well as post-marketing commitment and potential additional formulation work. Takeda's R&D team works closely with the commercial functions to maximize the value of marketed products and reflect commercial insights in its R&D strategies and portfolio.

Major progress on R&D events since April 2023 are listed as follows:

R&D pipeline

Gastrointestinal and Inflammation

In Gastrointestinal and Inflammation, Takeda focuses on delivering innovative, life-changing therapeutics for patients with gastrointestinal diseases, including those of the liver as well as immune-mediated inflammatory diseases. Takeda is maximizing the potential of our inflammatory bowel disease (IBD) franchise around ENTYVIO, including development of a subcutaneous formulation and expansion into other indications such as active chronic pouchitis. Takeda is also expanding its position with GATTEX/REVESTIVE to support further potential geographic expansion. Furthermore, Takeda is progressing a pipeline built through in-house discovery, partnerships and business development, exploring opportunities in inflammatory diseases (specifically in gastric, dermatological and rheumatic disorders, along with select rare hematological & renal diseases), liver diseases, and motility disorders. TAK-279 is an example of an acquisition through business development of a late-stage, potential best-in-class oral allosteric tyrosine kinase 2 (TYK2) inhibitor with potential to treat multiple immune-mediated inflammatory diseases. Fazirsiran (TAK-999) is an example of an addition through partnership and a potential first-in-class RNAi for alpha-1 antitrypsin-deficiency associated liver disease in late-stage development.

Note: ADZYNMA (TAK-755) and mezagitamab (TAK-079) have been developed in Gastrointestinal and Inflammation starting from FY2023 Q4.

ENTYVIO / Generic name: vedolizumab

- In April 2023, Takeda announced that the U.S. Food and Drug Administration (FDA) accepted for review its Biologics License Application (BLA) resubmission for the investigational subcutaneous (SC) administration of ENTYVIO for maintenance therapy in adults with moderately to severely active ulcerative colitis (UC) after induction therapy with ENTYVIO intravenous (IV). The resubmission was intended to address FDA feedback in a December 2019 Complete Response Letter (CRL). Since receiving the CRL Takeda worked closely with the FDA to address the Agency's feedback; and this resubmission package included additional data collected to investigate the use of subcutaneous administration of ENTYVIO. The contents of the letter were unrelated to the IV formulation of ENTYVIO, the clinical safety and efficacy data, and conclusions from the pivotal VISIBLE 1 trial supporting the ENTYVIO SC BLA. VISIBLE 1 assessed the safety and efficacy of a SC formulation of ENTYVIO as maintenance therapy in 216 adult patients with moderately to severely active UC who achieved clinical response at week 6 following two doses of open-label ENTYVIO IV therapy at weeks 0 and 2. The primary endpoint was clinical remission at week 52, which was defined as a total Mayo score of ≤ 2 and no subscore >1 . In September 2023, Takeda announced that the FDA approved a SC administration of ENTYVIO for maintenance therapy in adults with moderately to severely active UC after induction therapy with ENTYVIO IV.
- In September 2023, Takeda announced that the FDA accepted for review its BLA for the investigational SC administration of ENTYVIO for maintenance therapy in adults with moderately to severely active Crohn's disease (CD) after induction therapy with ENTYVIO IV. The BLA package is based on data from VISIBLE 2 trial that assessed the safety and efficacy of an SC formulation of ENTYVIO as maintenance therapy compared to placebo in 409 adult patients with moderately to severely active CD who achieved clinical response at week 6 following two doses of open-

label ENTYVIO IV therapy at weeks 0 and 2. The primary endpoint was clinical remission at week 52, which was defined as CD Activity Index (CAI) score ≤ 150 .

- In September 2023, Takeda announced that it received an approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) for a partial change to the marketing authorization status of ENTYVIO Pens for S.C. Injection 108 mg /Syringes for S.C. Injection 108 mg (ENTYVIO SC) as a maintenance therapy for moderate to severe active Crohn's disease (CD) with inadequate response to conventional treatment. This approval is based on the results of the MLN0002SC-3031 and MLN0002SC-3030 clinical trials, which are international Phase 3 trials that evaluated the efficacy and safety of ENTYVIO SC as a maintenance therapy in moderate to severe active CD.

ALOFISEL / Generic name: darvadstrocel

- In October 2023, Takeda announced that the Phase 3 ADMIRE-CD II study, assessing the efficacy and safety of ALOFISEL for the treatment of complex Crohn's Perianal Fistulas (CPF), did not meet its primary endpoint of combined remission at 24 weeks, based on topline data. The safety profile for darvadstrocel was consistent with prior studies and there were no new safety signals identified. Full results of the study will be presented at a future medical meeting or published in a peer-reviewed journal. ALOFISEL is approved in the European Union (EU), Israel, Switzerland, Serbia, United Kingdom and Japan based on positive data from the previously completed ADMIRE-CD study.

ADZYNMA / Generic name: apadamtase alfa/cinaxadamtase alfa (Development code: TAK-755)

- In June 2023, Takeda presented favorable interim results from a global pivotal Phase 3 randomized, controlled, open-label, crossover trial evaluating the safety and efficacy of TAK-755 replacement therapy for the prophylactic treatment of congenital thrombotic thrombocytopenic purpura (cTTP), and pharmacokinetics (PK) characteristics of TAK-755, as well as long-term data on TAK-755 prophylaxis from a Phase 3b continuation study at the International Society on Thrombosis and Haemostasis (ISTH) 2023 Congress. In the pivotal trial, no patient had an acute TTP event while receiving TAK-755 prophylactic treatment. TAK-755 also reduced the incidence of thrombocytopenia by 60%, as compared to plasma-based therapy (hazard ratio [HR] 0.40; 95% confidence interval [CI]; 0.3- 0.7). Treatment-emergent adverse events (TEAEs) were reported in 10.3% of patients ages 12-68 receiving TAK-755 compared to 50% of patients receiving plasma-based therapy, demonstrating a favorable safety and tolerability profile with a potential safety advantage over plasma-based therapies. PK characteristics of ADAMTS13 after a single infusion (0-168 hours) were evaluated and compared to plasma-based therapy in 36 cTTP patients aged 12 and older. Patients receiving TAK-755 achieved a five-fold increase in their ADAMTS13 activity levels compared to those receiving plasma-based therapy (Cmax 100% activity for TAK-755 vs. 19% activity for plasma-based therapy) and lower variability (23.8% vs. 56% coefficient of variation [CV], respectively). Also, the results of an interim analysis of the Phase 3b continuation study, evaluating the safety and efficacy of long-term TAK-755 prophylaxis in 29 patients with cTTP, demonstrated a consistently favorable safety profile with TAK-755 prophylaxis and no development of neutralizing antibodies. Zero acute TTP events occurred during TAK-755 prophylaxis, and the incidence rates of subacute TTP events and TTP manifestations were comparable to those with TAK-755 prophylaxis in the pivotal study.
- In August 2023, Takeda announced that it filed an application for manufacturing and marketing approval for TAK-755 for the expected indication of cTTP with the Japanese Ministry of Health, Labour and Welfare (MHLW). The application is based on the interim analysis of the global Phase 3 clinical trial 281102 primarily focusing on patients with cTTP, including five Japanese individuals, and the Phase 3b continuation trial TAK-755-3002. In these trials, TAK-755 was evaluated for its efficacy and safety as a treatment for cTTP.
- In November 2023, Takeda announced that the U.S. Food and Drug Administration (FDA) approved ADZYNMA for the prophylactic and on-demand treatment of adult and pediatric patients with cTTP. The FDA previously granted Fast Track Designation, Orphan Drug Designation, and Rare Pediatric Disease Designation in cTTP, as well as Priority Review for ADZYNMA's Biologic License Application (BLA). The FDA granted the company a Rare Pediatric Disease Voucher for the approval of ADZYNMA. The FDA approval of ADZYNMA was supported by the totality of the evidence provided by the analysis of efficacy, pharmacokinetic, safety and tolerability data from the first randomized, controlled, open-label, crossover Phase 3 trial in cTTP as well as by data from the continuation trial. ADZYNMA is the first and

only FDA-approved recombinant ADAMTS13 (rADAMTS13) designed to address an unmet medical need in people with cTTP by replacing the deficient ADAMTS13 enzyme.

Development Code: TAK-279

- In November 2023, Takeda presented positive results from its randomized, double-blind, placebo-controlled, Phase 2b trial evaluating TAK-279 in patients with active psoriatic arthritis during a late-breaking session at the American College of Rheumatology (ACR) Convergence 2023. The study met its primary endpoint with a statistically significant proportion of patients, 53.3% (15 mg) and 54.2% (30 mg), treated once-daily with TAK-279 achieving at least an American College of Rheumatology 20 (ACR 20) response compared to 29.2% in the placebo arm at week 12 ($p = 0.002$). TAK-279 demonstrated improvements in key secondary endpoints and the safety and tolerability profile in the trial was consistent with that observed in the Phase 2b plaque psoriasis clinical study. Based on the Phase 2b results, Takeda intends to initiate a Phase 3 development program of TAK-279 in psoriatic arthritis. Takeda also initiated a Phase 3 development program of TAK-279 in plaque psoriasis in Q3 FY2023 and plans to evaluate TAK-279 in Crohn's disease, ulcerative colitis and additional immune-mediated inflammatory diseases.

Development code: TAK-721 (Planned trade name: Eohilia) / Generic name: budesonide

- In September 2023, Takeda announced that the U.S. Food and Drug Administration (FDA) accepted for review its New Drug Application (NDA) resubmission for TAK-721 (budesonide oral suspension) which is being investigated for the short-term treatment of eosinophilic esophagitis (EoE). The resubmission is intended to address previous FDA feedback to Takeda's original NDA submission.

Neuroscience

In Neuroscience, Takeda is focusing its R&D investments on potentially transformative treatments for neurological and neuromuscular diseases of high unmet need and building its pipeline through a combination of in-house expertise and partnerships. By harnessing advances in disease biology understanding, translational tools, and innovative modalities, Takeda is primarily focusing on rare neurology, in particular, on potential investigative therapies for sleep-wake disorders such as narcolepsy and idiopathic hypersomnia with a franchise of orexin-2 receptor agonists (TAK-861, danavorexton (TAK-925), etc.), rare epilepsies with soticlestat (TAK-935) and central nervous system (CNS) and somatic symptoms of Hunter Syndrome with pabinafusp alfa (TAK-141). Additionally, Takeda makes targeted investments to investigate well-defined segments of neuromuscular diseases, neurodegenerative diseases and movement disorders.

Oncology

In Oncology, we aspire to cure cancer, with inspiration from patients and innovation from everywhere. We are focused on: (1) building on our legacy in hematologic malignancies with marketed products (NINLARO, ADCETRIS, and ICLUSIG, etc.); (2) growing a solid tumor portfolio with marketed products (ALUNBRIG and FRUZAQLA [marketed in the U.S., development in other regions outside of mainland China, Hong Kong and Macau ongoing]); and (3) advancing a cutting-edge pipeline of highly innovative assets and platforms.

CABOMETRYX / Generic name: cabozantinib

- In January 2024, Takeda announced that the detailed results from CONTACT-02, a phase 3 pivotal study led by Exelixis, evaluating CABOMETRYX in combination with atezolizumab compared with a second novel hormonal therapy (NHT) in patients with metastatic castration-resistant prostate cancer (mCRPC) and measurable extra-pelvic soft tissue disease who have progressed on one prior NHT were presented during Oral Abstract Session at the American Society of Clinical Oncology 2024 Genitourinary Cancers Symposium (ASCO GU). For the primary endpoint of progression-free survival (PFS), at a median follow-up of 14.3 months for the PFS ITT (intent-to-treat) population ($n=400$), the hazard ratio (HR) was 0.65 (95% confidence interval [CI]: 0.50-0.84; $p=0.0007$); the median PFS (mPFS) was 6.3 months for CABOMETRYX in combination with atezolizumab compared with 4.2 months for NHT. This was nearly identical to the PFS for the ITT population ($n=507$): HR was 0.64 (95% CI: 0.50-0.81, $p=0.0002$). At a median follow-up of 12.0 months for the ITT population, the median overall survival (OS), the other primary endpoint, was 16.7 months for CABOMETRYX in combination with atezolizumab compared with 14.6 months for second NHT (HR: 0.79; 95% CI: 0.58-1.07; $p=0.13$), showing a trend toward OS improvement. The safety profiles of CABOMETRYX and atezolizumab observed in this trial were consistent with their known safety profiles as monotherapies, and no new safety concerns were identified with the combination regimen.

ADCETRIS / Generic name: brentuximab vedotin

- In October 2023, Takeda announced that the European Commission (EC) approved ADCETRIS in combination with doxorubicin, vinblastine and dacarbazine (AVD) to treat adult patients with previously untreated CD30+ Stage III Hodgkin lymphoma. The decision follows a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) in September, 2023. The approval is based on the results of the randomized Phase 3 ECHELON-1 trial designed to compare ADCETRIS plus AVD to doxorubicin, bleomycin, vinblastine, and dacarbazine (ABVD) as a therapy in adult patients with previously untreated Stage III or IV Hodgkin lymphoma. The trial met its primary endpoint of modified progression-free survival (PFS), as well as its key secondary endpoint of overall survival (OS), demonstrating a statistically significant improvement in OS in adult patients with previously untreated Stage III or IV classical Hodgkin lymphoma treated with ADCETRIS+AVD. The safety profile of ADCETRIS was consistent with previous studies, and no new safety signals were observed.
- In November 2023, Takeda announced that it received an approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) for a partial change in approved items of the manufacturing and marketing approval of ADCETRIS with the new indication of relapsed or refractory CD30-positive cutaneous T-cell lymphoma (CTCL). The approval is based on the results of the Phase 3 ALCANZA trial conducted outside of Japan as well as the Japanese Phase 2 investigator-initiated SGN-35-OU trial in patients with relapsed or refractory CD30-positive CTCL.

NINLARO / Generic name: ixazomib

- In September 2023, Takeda announced that it submitted a New Drug Application (NDA) to the Japanese Ministry of Health, Labour and Welfare (MHLW) for NINLARO capsules 0.5 mg as an additional dosage form of NINLARO (Capsules 2.3 mg/3 mg/4 mg). Aiming to achieve more appropriate dose adjustment in maintenance therapy for patients with multiple myeloma, Takeda filed this application to provide patients with a new treatment option (1.5 mg dose (0.5 mg/capsule x 3)) using a low-dose formulation of NINLARO.

EXKIVITY / Generic name: mobocertinib

- In October 2023, Takeda announced that, following discussions with the U.S. Food and Drug Administration (FDA), it will be working with the FDA towards a voluntary withdrawal of EXKIVITY in the U.S. for adult patients with epidermal growth factor receptor (EGFR) exon20 insertion mutation-positive (insertion+) locally advanced or metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on or after platinum-based chemotherapy. Takeda intends to similarly initiate voluntary withdrawal globally where EXKIVITY is approved and is working with regulators in other countries where it is currently available on next steps. This decision was based on the outcome of the Phase 3 EXCLAIM-2 confirmatory trial, which did not meet its primary endpoint and thus did not fulfill the confirmatory data requirements of the accelerated approval granted by the U.S. FDA nor the conditional marketing approvals granted in other countries. The EXCLAIM-2 trial was a Phase 3, multicenter, open-label study designed to investigate the safety and efficacy of EXKIVITY as a monotherapy versus platinum-based chemotherapy in first-line EGFR exon20 insertion+ locally advanced or metastatic NSCLC. No new safety signals were observed in the EXCLAIM-2 trial. Full data from the trial will be presented at an upcoming medical meeting or published in a peer-reviewed journal.

FRUZAQLA / Generic name: fruquintinib

- In June 2023, Takeda and HUTCHMED (China) Limited announced that the European Medicines Agency (EMA) validated and accepted for regulatory review the marketing authorization application (MAA) for fruquintinib for the treatment of adult patients with previously treated metastatic colorectal cancer (mCRC). If approved, fruquintinib will be the first and only highly selective and potent inhibitor of vascular endothelial growth factor receptors (VEGFR) -1, -2 and -3 approved in the European Union (EU) for previously treated mCRC. The MAA for fruquintinib includes results from the global Phase 3 FRESCO-2 clinical trial along with data from the Phase 3 FRESCO clinical trial.
- In June 2023, Takeda and HUTCHMED (China) Limited announced that results of the Phase 3 FRESCO-2 study evaluating fruquintinib in patients with previously treated mCRC were published in *The Lancet*. FRESCO-2 is a global Phase 3 clinical trial (MRCT) conducted in the U.S., Europe, Japan and Australia investigating fruquintinib plus best supportive care (BSC) vs placebo plus BSC in patients with previously treated mCRC. The FRESCO-2 study met its primary and key secondary endpoints, demonstrating that treatment with fruquintinib resulted in a statistically significant and clinically meaningful improvement in overall survival (OS) and progression-free survival (PFS), respectively. The safety profile of fruquintinib in FRESCO-2 was consistent with previously reported fruquintinib studies.

- In September 2023, Takeda announced that it submitted a New Drug Application (NDA) to the Japanese Ministry of Health, Labour and Welfare (MHLW) for fruquintinib for the treatment of previously treated mCRC. The NDA for fruquintinib is based on the global Phase 3 FRESCO-2 clinical trial and the Phase 3 FRESCO clinical trial.
- In November 2023, Takeda announced that the U.S. Food and Drug Administration (FDA) approved FRUZAQLA for adults with mCRC who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type and medically appropriate, an anti-EGFR therapy. FRUZAQLA is the first and only selective inhibitor of all three VEGF receptor kinases approved in the U.S. for previously treated mCRC regardless of biomarker status. The approval of FRUZAQLA is based on data from two large Phase 3 trials: the global FRESCO-2 clinical trial along with the FRESCO clinical trial conducted in China.

Rare Genetics and Hematology

In Rare Genetics and Hematology, Takeda focuses on several areas of high unmet medical need. In hereditary angioedema, Takeda aspires to transform the treatment paradigm, including through TAKHZYRO, with continued investment in lifecycle management programs. In rare hematology, Takeda focuses on addressing today's needs in the treatment of bleeding disorders, including through ADVATE and ADYNOVATE/ADYNOVI. In addition, Takeda aims to redefine the management of post-transplant cytomegalovirus (CMV) infection/disease with LIVTENCITY. Takeda commits to fulfilling our vision to deliver life-transforming medicines to patients with rare diseases.

ADYNOVATE/ADYNOVI / Generic name: antihemophilic factor (recombinant), PEGylated

- In June 2023, Takeda announced that it received an approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) for a partial change in approved items of the manufacturing and marketing approval of ADYNOVATE for dosage and administration. This approval will contribute driving personalized treatments by adjusting dosage and administration including dosing amount and intervals, depending on individual patient's clinical presentation and activity level. The approval is based primarily on the results of the global Phase 3 CONTINUATION study and Phase 3 PROPEL study conducted outside of Japan.

OBIZUR / Generic name: Susoctocog Alfa (recombinant)

- In June 2023, Takeda announced that it has submitted a marketing authorization application to the Japanese Ministry of Health, Labour and Welfare (MHLW) for Susoctocog Alfa (recombinant) for the control of bleeding in patients with acquired hemophilia A (AHA). The application is based primarily on a Japanese Phase 2/3 trial in adult Japanese patients with AHA and a Phase 2/3 trial conducted outside of Japan in non-Japanese adult patients with AHA.

LIVTENCITY / Generic name: maribavir

- In November 2023, Takeda announced that it submitted a New Drug Application (NDA) to the Japanese Ministry of Health, Labour and Welfare (MHLW) for maribavir for the treatment of patients with post-transplant (including hematopoietic stem cell transplant) cytomegalovirus (CMV) infection/disease. The NDA is primarily based on the Japanese Phase 3 open-label trial in patients with CMV infection who underwent hematopoietic stem cell transplant (HSCT) or solid organ transplant (SOT), and the Phase 3 open-label SOLSTICE trial conducted outside of Japan in patients with CMV infection refractory or resistant to prior anti-CMV treatment who underwent HSCT or SOT.
- In December 2023, Takeda announced that LIVTENCITY was approved by the National Medical Products Administration (NMPA) of China for the treatment of adult patients with post- HSCT or SOT CMV infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet. The NMPA approval is based on the results of the Phase 3 SOLSTICE trial. LIVTENCITY was granted Breakthrough Therapy Designation by China Center for Drug Evaluation (CDE) in 2021. LIVTENCITY is the first and only inhibitor of CMV-specific UL97 protein kinase in China for this indication.

Plasma-Derived Therapies (PDT)

Takeda has created a dedicated PDT business unit with a focus to manage the business end-to-end, from plasma collection to manufacturing, R&D, and commercialization. In PDT, we aspire to develop life-saving plasma derived treatments which are essential for patients with a variety of rare and complex chronic diseases. The dedicated R&D organization in PDT is charged with maximizing the value of existing therapies, identifying new targeted therapies, and optimizing efficiencies of current product manufacturing. Near-term, our priority is focused on delivering value from our broad immunoglobulin portfolio (HYQVIA, CUVITRU, GAMMAGARD and GAMMAGARD S/D) through pursuit of new indications, geographic expansions, and enhanced patient experience through integrated healthcare technologies. In our hematology and specialty care portfolio, our priority is pursuing new indication and formulation development opportunities for PROTHROMPLEX (4F-PCC), FEIBA, CEPROTIN and ARALAST. Additionally, we are developing next generation immunoglobulin products with 20% fSCIg (TAK-881), IgG Low IgA (TAK-880) and pursuing other early stage opportunities (e.g. hypersialylated Immunoglobulin (hsIgG)) that would add to our diversified commercial portfolio of more than 20 therapeutic products distributed worldwide.

HYQVIA / Generic name: Immunoglobulin (IG) Infusion 10% (Human) w/ Recombinant Human Hyaluronidase for subcutaneous administration

- In April 2023, Takeda announced that the U.S. Food and Drug Administration (FDA) approved a supplemental biologics license application (sBLA) to expand the use of HYQVIA to treat primary immunodeficiency (PI) in children 2-16 years old. The FDA approval of HYQVIA for the treatment of PI in pediatric patients was based on evidence from a pivotal, prospective, open-label, non-controlled Phase 3 clinical trial that included 44 PI patients between the ages of 2 and 16. During the 12-month trial period, HYQVIA was shown to be efficacious with respect to the occurrence of acute serious bacterial infections (aSBIs), a primary endpoint. The mean aSBI rate per year was 0.04 and was statistically significantly lower (with an upper 1-sided 99% confidence interval of 0.21, $p < 0.001$) than the predefined success rate of less than one aSBI per subject per year, favoring efficacy of HYQVIA treatment in pediatric subjects with PI diseases. Results from the interim data analysis, where all subjects completed 12 months of participation (one year of observation period) in the study, indicated similar safety profiles to adults.
- In June 2023, Takeda announced full results from the pivotal Phase 3 ADVANCE-CIDP 1 clinical trial investigating HYQVIA as maintenance therapy in adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP). ADVANCE-CIDP 1 is a Phase 3, prospective, randomized, double-blind, multicenter, placebo-controlled study in which adults with stable CIDP on intravenous immunoglobulin (IVIG) were randomized 1:1 to be switched to HYQVIA (n=62) or placebo (n=70) and received their assigned treatment for six months or until relapse or study withdrawal. The primary endpoint was proportion of participants who experienced a relapse defined as worsening of CIDP symptoms as measured by Inflammatory Neuropathy Cause and Treatment (INCAT). Secondary endpoints included patient proportion experiencing functional worsening, time to relapse, change from pre-subcutaneous treatment baseline in Rasch-built Overall Disability Scale (R-ODS) centile score and safety. Results showed a clinically significant reduction in relapse rate with HYQVIA vs placebo (9.7% vs. 31.4%, respectively; $p = 0.0045$) and other analysis showed delayed time to relapse with HYQVIA vs. placebo. Favorable data across other endpoints from the study and favorable tolerability were also observed. These findings were presented at the 2023 Peripheral Nerve Society (PNS) Annual Meeting in Denmark in June 2023, and simultaneously published in *the Journal of the Peripheral Nervous System (JPNS)*.
- In January 2024, Takeda announced that the FDA approved HYQVIA for the treatment of CIDP as maintenance therapy to prevent the relapse of neuromuscular disability and impairment in adult patients. The approval is based on results from ADVANCE-CIDP 1 clinical trial and ADVANCE-CIDP 3, a single-arm, open-label, extension study. HYQVIA is the only FDA-approved combination of immunoglobulin (IG) and hyaluronidase, which makes it a facilitated subcutaneous immunoglobulin (SCIg) infusion. For adults with CIDP, HYQVIA can be infused up to once monthly (every two, three or four weeks) due to the hyaluronidase component, which facilitates the dispersion and absorption of large IG volumes in the subcutaneous space between the skin and the muscle. Because it is delivered subcutaneously, HYQVIA can be administered by a healthcare professional in a medical office, infusion center or at a patient's home. In addition, it can be self-administered after appropriate patient or caregiver training.
- In January 2024, Takeda [announced](#) that the European Commission (EC) approved HYQVIA as maintenance therapy in patients of all ages with CIDP after stabilization with IVIG therapy. The approval is based on data from the pivotal Phase 3 ADVANCE-CIDP 1 clinical trial, which evaluated efficacy and safety of HYQVIA as maintenance therapy to prevent relapse in patients with CIDP.

CEPROTIN / Generic name: Human Dry Protein C Concentrate (Development code: TAK-662)

- In April 2023, Takeda announced that it submitted a New Drug Application (NDA) to the Japanese Ministry of Health, Labour and Welfare (MHLW) for manufacturing and marketing approval of human dry protein C concentrate (TAK-662) for the treatment of venous thromboembolism and purpura fulminans caused by congenital protein C deficiency, as well as for the suppression of thrombi. The application is based primarily on a Phase 1/2 trial in Japanese patients with congenital protein C deficiency and two Phase 2/3 trials (IMAG-098 and 400101) outside of Japan in patients with congenital protein C deficiency. In these trials, TAK-662 demonstrated its efficacy and safety as a treatment for congenital protein C deficiency.

CUVITRU / Generic name: Immunoglobulin (IG) Infusion 20% (Human) for subcutaneous administration

- In September 2023, Takeda announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) approved the use of CUVITRU in patients aged 2 years and older with agammaglobulinemia or hypogammaglobulinemia, disorders characterized by very low or absent levels of antibodies and an increased risk of serious recurring infection caused by primary immunodeficiency (PID) or secondary immunodeficiency (SID). The approval marks Takeda's first subcutaneous immunoglobulin (SCIG) therapy for patients in Japan. The approval is based on results from a Phase 3 clinical trial that evaluated the efficacy, safety, tolerability and pharmacokinetics of CUVITRU in Japanese patients with PID, as well as two Phase 2/3 clinical trials conducted in patients with PID in North America and Europe. Results from the clinical trial in 17 patients in Japan confirmed its efficacy and safety profile. No serious or severe adverse events were reported, and CUVITRU was well-tolerated. The most frequently reported adverse reactions were headache and injection site swelling in four patients (23.5%) and injection site erythema in three patients (17.6%) during CUVITRU treatment. Previously reported clinical trial results also confirmed the efficacy and safety of CUVITRU.

GAMMAGARD LIQUID / Generic name: Immunoglobulin (IG) Infusion 10% (Human)

- In January 2024, Takeda announced that the U.S. Food and Drug Administration (FDA) approved GAMMAGARD LIQUID as an intravenous immunoglobulin (IVIG) therapy to improve neuromuscular disability and impairment in adults with chronic inflammatory demyelinating polyneuropathy (CIDP). It can be used as induction therapy, which includes an induction dose and maintenance doses. For treatment of CIDP, GAMMAGARD LIQUID has not been studied in immunoglobulin-naïve patients nor as maintenance therapy has not been studied for periods longer than 6 months. The approval is based on results from a prospective, open-label, single-arm, multicenter ADVANCE-CIDP 2 clinical trial that evaluated the efficacy and safety of GAMMAGARD LIQUID in adults with CIDP who developed a relapse in HYQVIA's ADVANCE-CIDP 1 trial.

Vaccine

In Vaccines, Takeda is applying innovation to tackle some of the world's most challenging infectious diseases such as dengue (QDENG (development code: TAK-003)), COVID-19 (NUVAXOVID). To support the expansion of our pipeline and the development of our programs, we have entered into partnerships with government organizations in Japan and the U.S., and leading global institutions. Such partnerships have been essential in building the critical capabilities that will be necessary to deliver on our programs and realize their full potential.

QDENG / Generic name: Dengue tetravalent vaccine [live, attenuated] (Development code: TAK-003)

- In July 2023, Takeda announced that it voluntarily withdrew the U.S. Biologics License Application (BLA) for TAK-003, following discussions with the U.S. Food and Drug Administration (FDA) on aspects of data collection, which cannot be addressed within the current BLA review cycle. The future plan for TAK-003 in the U.S. will be further evaluated given the need for travelers and those living in dengue-endemic areas of the U.S., such as Puerto Rico. The efficacy and safety profiles of TAK-003 have been demonstrated through a robust clinical trial program, including a 4.5-year Phase 3 study of over 20,000 children and adolescents living in eight dengue endemic areas. The study was designed per World Health Organization (WHO) guidance for a second-generation dengue vaccine, and it considered the need to achieve high levels of subject retention and protocol compliance in endemic regions. The vaccine is approved in multiple endemic and non-endemic countries, with more approvals expected over the coming years.
- In October 2023, Takeda announced that the WHO Strategic Advisory Group of Experts on Immunization (SAGE) shared recommendations for use of QDENG. SAGE made the following recommendations:
 - The vaccine to be considered for introduction in settings with high dengue disease burden and high transmission intensity to maximize the public health impact and minimize any potential risk in seronegative persons.

- The vaccine to be introduced to children aged 6 to 16 years of age. Within this age range, the vaccine should be introduced about 1-2 years prior to the age-specific peak incidence of dengue-related hospitalizations. The vaccine should be administered in a 2-dose schedule with a 3-month interval between doses.
- The vaccine introduction should be accompanied by a well-designed communication strategy and community engagement.

SAGE reviewed data across 19 Phase 1, 2 and 3 trials with more than 28,000 children and adults, including the pivotal Phase 3 Tetravalent Immunization against Dengue Efficacy Study (TIDES) trial, which was designed according to the WHO’s guidance for a second-generation dengue vaccine.

The WHO will consider the SAGE recommendation and is expected to update its position paper on dengue vaccines to include final guidance on the use of QDENG A in public vaccination programs.

Building a sustainable research platform / Enhancing R&D collaboration

In addition to our concentrated efforts to increase our in-house R&D capabilities, external partnerships with third-party partners are a key component of our strategy for enhancing our R&D pipeline. Our strategy to expand and diversify our external partnerships allows us to take part in research of a wide variety of new products and increases the chances that we will be able to take part in a major research-related breakthrough.

- In August 2023, Takeda announced that it entered into an exclusive licensing agreement with ImmunoGen, Inc. (ImmunoGen) to develop and commercialize mirvetuximab soravtansine-gynx (MIRV) for the Japanese market. MIRV is an intravenous injection antibody-drug conjugate (ADC), in which a microtubule inhibitor is linked to an anti-folate receptor- α (FR α) antibody. It is the first ADC developed for the treatment of ovarian cancer. MIRV is approved under accelerated approval in the U.S. for the treatment of adult patients with FR α positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. MIRV was the first medicine to show a significant prolongation of overall survival (OS) compared with conventional chemotherapy for the treatment of platinum-resistant relapsed or refractory ovarian cancer in a phase 3 MIRASOL study, conducted outside of Japan.
- In January 2024, Takeda and Protagonist Therapeutics, Inc. announced the signing of a worldwide license and collaboration agreement for the development and commercialization of rusfertide, an investigational injectable hepcidin mimetic peptide of the natural hormone hepcidin, currently in a pivotal Phase 3 trial, VERIFY, for the treatment of Polycythemia Vera (PV). Discovered through Protagonist's peptide technology platform, rusfertide’s mechanism of action is thought to regulate iron homeostasis and control the absorption, storage and distribution of iron in the body. The randomized portion of the Phase 2 REVIVE study of rusfertide in PV achieved its primary endpoint. The long-term follow-up data from the 2-year open label extension were presented at the American Society of Hematology 2023 Annual Meeting, which showed durable hematocrit control, decreased phlebotomy use, long-term tolerability and no new safety signals in patients with PV. Protagonist will remain responsible for research and development through the completion of the Phase 3 clinical trial and U.S regulatory approval. Takeda has rights for ex-U.S. development and is responsible for leading global commercialization activities.

(4) Major Facilities

The following shows a significant change in new facility construction for the nine-month period ended December 31, 2023.

Classification	Name or Subsidiaries' Company Name [Main Location]	Operating Segment	Details	Budget* ¹		Financing	Schedule	
				Total JPY (millions)	Paid JPY (millions)		Commencement	Completion
Construction	Baxalta US Inc. [Los Angeles, CA, U.S.A.]	Pharmaceuticals	Manufacturing	32,382	331	Funds on hand	January 2024	June 2027

*1 The budget is calculated based on the exchange rates as of December 31, 2023.

3. Material Contracts

There were no material contracts executed during the three-month period ended December 31, 2023.

III. Information on the Company

1. Information on the Company's Shares

(1) Total number of shares and other related information

1) Total number of shares

Class	Total number of shares authorized to be issued (Shares)
Common stock	3,500,000,000
Total	3,500,000,000

2) Number of shares issued

Class	Number of shares outstanding (As of December 31, 2023)	Number of shares outstanding as of the filing date (February 2, 2024)	Stock exchange on which the Company is listed	Description
Common stock	1,582,392,825	1,582,399,825	Tokyo (Prime Market), Nagoya (Premier Market), Fukuoka, Sapporo, and New York	The number of shares per one unit of shares is 100 shares.
Total	1,582,392,825	1,582,399,825	—	—

(Note1) The Company's American Depositary Shares (ADS) are listed on the New York Stock Exchange.

(Note2) The number of shares outstanding as of the filing date does not include shares issued upon exercise of stock acquisition rights from February 1, 2024 to the filing date of Quarterly Securities Report (February 2, 2024).

(2) Status of stock acquisition rights

1) Contents of stock option plans

Not applicable.

2) Status of other stock acquisition rights

Not applicable.

(3) Exercise status of bonds with stock acquisition rights containing a clause for exercise price adjustments

Not applicable.

(4) Changes in the total number of issued shares and the amount of share capital and capital reserve

Date	Change in the total number of issued shares (Thousand of shares)	Balance of the total number of issued shares (Thousand of shares)	Change in share capital JPY (millions)	Balance of share capital JPY (millions)	Change in capital reserve JPY (millions)	Balance of capital reserve JPY (millions)
From October 1, 2023 to December 31, 2023	20	1,582,393	40	1,676,543	40	1,668,555

(Note) The increases are due to the exercise of stock acquisition rights.

(5) Major shareholders

No information required in the 3rd quarter.

(6) Information on voting rights

1) Total number of shares

Classification	As of December 31, 2023		
	Number of shares (Shares)	Number of voting rights (Units)	Description
Shares without voting rights	—	—	—
Shares with restricted voting rights (Treasury stock and other)	—	—	—
Shares with restricted voting rights (Others)	—	—	—
	(Treasury stock)		
	Common stock	7,513,000	—
Shares with full voting rights (Treasury stock and other)	(Crossholding stock)		
	Common stock	287,000	—
Shares with full voting rights (Others)	Common stock	1,573,040,900	15,730,409
			Shares less than one unit (100 shares)
Shares less than one unit	Common stock	1,551,925	—
Number of issued shares		1,582,392,825	—
Total number of voting rights		—	15,730,409

(Note1) "Shares with full voting rights (Others)" includes 3,630,200 (voting rights: 36,302) and 2,257,800 (voting rights: 22,578) of the shares held by the ESOP and BIP trust, respectively.

(Note2) "Shares less than one unit" includes 14 of the shares as the treasury stock, and 139 and 219 of the shares held by the ESOP and BIP trust, respectively.

2) Treasury stock and other

As of December 31, 2023					
Name of shareholders	Address	Number of shares held under own name (Shares)	Number of shares held under the name of others (Shares)	Total shares held (Shares)	Percentage of total issued shares issued (%)
(Treasury stock)					
Takeda Pharmaceutical Company Limited	1-1, Doshomachi 4- chome, Chuo-ku, Osaka	7,513,000	—	7,513,000	0.47
(Crossholding stock)					
Amato Pharmaceutical Products, Ltd.	5-3, Shinsenri Higashi- machi 1-chome, Toyonaka-city, Osaka	275,000	—	275,000	0.02
Watanabe Chemical, Co., Ltd.	6-1, Hiranomachi 3- chome, Chuo-ku, Osaka-city, Osaka	12,000	—	12,000	0.00
Total		7,800,000	—	7,800,000	0.49

(Note) In addition to 14 shares of the above treasury stock and shares less than one unit, 3,630,339 of the shares held by the ESOP trust and 2,258,019 of the shares held by the BIP trust are included in treasury stock on the condensed interim consolidated financial statements.

2. Members of the Board of Directors

No changes from the latest Annual Securities Report.

IV. Financial Information

Basis of Preparation of the Condensed Interim Consolidated Financial Statements

Takeda has prepared the condensed interim consolidated financial statements in accordance with IAS 34 “Interim Financial Reporting” based on the provision of Article 93 of Ordinance on Terminology, Forms and Preparation Methods of Quarterly Consolidated Financial Statements (Ordinance of the Ministry of Finance No. 64, 2007 in Japan).

1. Condensed Interim Consolidated Financial Statements
(1) Condensed Interim Consolidated Statements of Profit or Loss

	Note	JPY (millions, except per share data)			
		Nine-month Period Ended December 31,		Three-month Period Ended December 31,	
		2022	2023	2022	2023
Revenue	4	3,071,322	3,212,893	1,096,551	1,111,186
Cost of sales		(934,300)	(1,044,177)	(335,973)	(379,481)
Selling, general and administrative expenses		(742,513)	(768,585)	(262,299)	(267,520)
Research and development expenses		(472,381)	(534,068)	(174,629)	(187,381)
Amortization and impairment losses on intangible assets associated with products	5	(409,219)	(507,003)	(135,576)	(137,338)
Other operating income		16,676	10,768	3,200	894
Other operating expenses	6	(127,643)	(145,685)	(44,284)	(35,446)
Operating profit		401,943	224,144	146,990	104,914
Finance income		55,130	46,101	41,679	22,550
Finance expenses		(126,765)	(172,663)	(79,749)	(67,329)
Share of profit (loss) of investments accounted for using the equity method		(3,133)	2,731	(1,767)	1,125
Profit before tax		327,175	100,313	107,153	61,260
Income tax (expenses) benefit	7	(41,273)	46,878	11,996	44,496
Net profit for the period		285,903	147,191	119,149	105,756
Attributable to:					
Owners of the Company		285,883	147,085	119,127	105,720
Non-controlling interests		19	106	22	36
Net profit for the period		285,903	147,191	119,149	105,756
Earnings per share (JPY)					
Basic earnings per share	8	184.32	94.10	76.63	67.38
Diluted earnings per share	8	182.65	93.17	75.86	66.70

See accompanying notes to condensed interim consolidated financial statements.

(2) Condensed Interim Consolidated Statements of Comprehensive Income

	JPY (millions)			
	Nine-month Period Ended December 31,		Three-month Period Ended December 31,	
	2022	2023	2022	2023
Net profit for the period	285,903	147,191	119,149	105,756
Other comprehensive income (loss)				
Items that will not be reclassified to profit or loss:				
Changes in fair value of financial assets measured at fair value through other comprehensive income	730	(1,383)	(4,554)	(7,920)
Remeasurement of defined benefit pension plans	12,977	(3,038)	(418)	(5,681)
	13,707	(4,421)	(4,972)	(13,602)
Items that may be reclassified subsequently to profit or loss:				
Exchange differences on translation of foreign operations	481,206	459,803	(553,986)	(319,417)
Cash flow hedges	(17,584)	22,746	15,616	24,760
Hedging cost	(12,107)	301	10,642	2,880
Share of other comprehensive income (loss) of investments accounted for using the equity method	(915)	(466)	170	(187)
	450,599	482,383	(527,558)	(291,964)
Other comprehensive income (loss) for the period, net of tax	464,306	477,963	(532,531)	(305,566)
Total comprehensive income (loss) for the period	750,209	625,154	(413,381)	(199,810)
Attributable to:				
Owners of the Company	750,193	625,030	(413,341)	(199,814)
Non-controlling interests	16	124	(40)	4
Total comprehensive income (loss) for the period	750,209	625,154	(413,381)	(199,810)

See accompanying notes to condensed interim consolidated financial statements.

(3) Condensed Interim Consolidated Statements of Financial Position

		JPY (millions)	
		As of March 31, 2023	As of December 31, 2023
	Note		
<u>ASSETS</u>			
Non-current assets:			
Property, plant and equipment		1,691,229	1,841,499
Goodwill		4,790,723	5,111,287
Intangible assets		4,269,657	4,097,022
Investments accounted for using the equity method		99,174	103,312
Other financial assets		279,683	269,606
Other non-current assets		63,325	54,703
Deferred tax assets		366,003	316,689
Total non-current assets		11,559,794	11,794,117
Current assets:			
Inventories		986,457	1,169,640
Trade and other receivables		649,429	716,230
Other financial assets		20,174	29,045
Income taxes receivable		32,264	26,849
Other current assets		160,868	179,393
Cash and cash equivalents		533,530	288,359
Assets held for sale		15,235	19,313
Total current assets		2,397,956	2,428,830
Total assets		13,957,750	14,222,947
<u>LIABILITIES AND EQUITY</u>			
<u>LIABILITIES</u>			
Non-current liabilities:			
Bonds and loans	9	4,042,741	4,293,872
Other financial liabilities		534,269	542,126
Net defined benefit liabilities		127,594	138,945
Income taxes payable		24,558	4,101
Provisions		55,969	13,619
Other non-current liabilities		65,389	72,473
Deferred tax liabilities		270,620	133,036
Total non-current liabilities		5,121,138	5,198,172
Current liabilities:			
Bonds and loans	9	339,600	370,292
Trade and other payables		649,233	483,666
Other financial liabilities		185,537	248,100
Income taxes payable		232,377	112,446
Provisions		508,360	482,467
Other current liabilities		566,689	585,197
Liabilities held for sale		144	—
Total current liabilities		2,481,940	2,282,168
Total liabilities		7,603,078	7,480,340

JPY (millions)

	Note	As of March 31, 2023	As of December 31, 2023
<u>EQUITY</u>			
Share capital		1,676,345	1,676,543
Share premium		1,728,830	1,730,138
Treasury shares		(100,317)	(51,253)
Retained earnings		1,541,146	1,396,838
Other components of equity		1,508,119	1,989,669
Equity attributable to owners of the Company		6,354,122	6,741,934
Non-controlling interests		549	673
Total equity		6,354,672	6,742,607
Total liabilities and equity		13,957,750	14,222,947

See accompanying notes to condensed interim consolidated financial statements.

(4) Condensed Interim Consolidated Statements of Changes in Equity

Nine-month period ended December 31, 2022 (From April 1 to December 31, 2022)

JPY (millions)													
Equity attributable to owners of the Company													
Other components of equity													
Note	Share capital	Share premium	Treasury shares	Retained earnings	Exchange differences on translation of foreign operations	Changes in fair value of financial assets measured at fair value through other comprehensive income	Cash flow hedges	Hedging cost	Remeasurements of defined benefit pension plans	Total other components of equity	Total equity attributable to owners of the Company	Non-controlling interests	Total equity
As of April 1, 2022	1,676,263	1,708,873	(116,007)	1,479,716	984,141	22,068	(65,901)	(6,135)	—	934,173	5,683,019	504	5,683,523
Effect of hyperinflation				(1,960)	4,121					4,121	2,161		2,161
Restated opening balance	1,676,263	1,708,873	(116,007)	1,477,756	988,263	22,068	(65,901)	(6,135)	—	938,294	5,685,180	504	5,685,684
Net profit for the period				285,883						—	285,883	19	285,903
Other comprehensive income (loss)					480,326	698	(17,584)	(12,107)	12,977	464,310	464,310	(4)	464,306
Comprehensive income (loss) for the period	—	—	—	285,883	480,326	698	(17,584)	(12,107)	12,977	464,310	750,193	16	750,209
Transactions with owners:													
Issuance of new shares	71	71								—	142		142
Acquisition of treasury shares		(5)	(27,056)							—	(27,062)		(27,062)
Disposal of treasury shares		0	1							—	1		1
Dividends	10			(278,321)						—	(278,321)		(278,321)
Transfers from other components of equity				22,402		(9,424)			(12,977)	(22,402)	—		—
Share-based compensation		45,823								—	45,823		45,823
Exercise of share-based awards		(42,727)	42,749							—	22		22
Total transactions with owners	71	3,162	15,693	(255,919)	—	(9,424)	—	—	(12,977)	(22,402)	(259,395)	—	(259,395)
As of December 31, 2022	1,676,334	1,712,036	(100,314)	1,507,720	1,468,588	13,341	(83,486)	(18,242)	—	1,380,202	6,175,978	520	6,176,498

See accompanying notes to condensed interim consolidated financial statements.

Nine-month period ended December 31, 2023 (From April 1 to December 31, 2023)

JPY (millions)														
Equity attributable to owners of the Company														
	Note						Other components of equity					Total equity attributable to owners of the Company	Non-controlling interests	Total equity
		Share capital	Share premium	Treasury shares	Retained earnings		Exchange differences on translation of foreign operations	Changes in fair value of financial assets measured at fair value through other comprehensive income	Cash flow hedges	Hedging cost	Remeasurements of defined benefit pension plans			
As of April 1, 2023		1,676,345	1,728,830	(100,317)	1,541,146	1,606,128	12,470	(87,352)	(23,127)	—	1,508,119	6,354,122	549	6,354,672
Net profit for the period					147,085						—	147,085	106	147,191
Other comprehensive income (loss)						459,256	(1,320)	22,746	301	(3,038)	477,945	477,945	18	477,963
Comprehensive income (loss) for the period		—	—	—	147,085	459,256	(1,320)	22,746	301	(3,038)	477,945	625,030	124	625,154
Transactions with owners:														
Issuance of new shares		198	198								—	395		395
Acquisition of treasury shares				(2,362)							—	(2,362)		(2,362)
Disposal of treasury shares			0	0							—	1		1
Dividends	10				(287,788)						—	(287,788)		(287,788)
Changes in ownership											—	—	(0)	(0)
Transfers from other components of equity					(3,605)	567				3,038	3,605	—		—
Share-based compensation			52,603								—	52,603		52,603
Exercise of share-based awards			(51,492)	51,426							—	(67)		(67)
Total transactions with owners		198	1,308	49,064	(291,393)	—	567	—	—	3,038	3,605	(237,218)	(0)	(237,219)
As of December 31, 2023		1,676,543	1,730,138	(51,253)	1,396,838	2,065,384	11,717	(64,606)	(22,826)	—	1,989,669	6,741,934	673	6,742,607

See accompanying notes to condensed interim consolidated financial statements.

(5) Condensed Interim Consolidated Statements of Cash Flows

	Notes	JPY (millions)	
		Nine-month Period Ended	
		December 31,	
		2022	2023
Cash flows from operating activities:			
Net profit for the period		285,903	147,191
Depreciation and amortization		502,990	541,258
Impairment losses		41,969	134,281
Equity-settled share-based compensation		45,823	52,683
Loss (gain) on sales and disposal of property, plant and equipment		(161)	1,988
Gain on divestment of business and subsidiaries		(959)	(441)
Change in fair value of financial assets and liabilities associated with contingent consideration arrangements, net		4,323	12,773
Finance (income) and expenses, net		71,635	126,563
Share of loss (profit) of investments accounted for using the equity method		3,133	(2,731)
Income tax expenses (benefit)		41,273	(46,878)
Changes in assets and liabilities:			
Decrease (increase) in trade and other receivables		6,856	(58,793)
Increase in inventories		(34,240)	(128,490)
Increase (decrease) in trade and other payables		(144,971)	20,587
Increase (decrease) in provisions		11,605	(138,669)
Decrease in other financial liabilities		(7,906)	(10,014)
Other, net		21,258	(47,242)
Cash generated from operations		848,529	604,064
Income taxes paid		(173,363)	(179,298)
Tax refunds and interest on tax refunds received		8,297	12,990
Net cash from operating activities		683,463	437,756
Cash flows from investing activities:			
Interest received		2,792	8,245
Dividends received		3,234	531
Acquisition of property, plant and equipment		(104,888)	(130,884)
Proceeds from sales of property, plant and equipment		80	8,604
Acquisition of intangible assets		(84,721)	(285,520)
Acquisition of investments		(5,441)	(4,724)
Proceeds from sales and redemption of investments		20,553	1,089
Proceeds from sales of business, net of cash and cash equivalents divested		—	365
Other, net		(219)	(82)
Net cash used in investing activities		(168,610)	(402,378)

	Notes	JPY (millions)	
		Nine-month Period Ended December 31,	
		2022	2023
Cash flows from financing activities:			
Net increase in short-term loans and commercial papers		—	280,000
Proceeds from issuance of bonds and long-term loans		—	100,000
Repayments of bonds and long-term loans		(281,585)	(320,817)
Proceeds from the settlement of cross currency interest rate swaps related to bonds		—	60,063
Acquisition of treasury shares		(26,929)	(2,326)
Interest paid		(86,563)	(78,685)
Dividends paid		(268,997)	(278,062)
Repayments of lease liabilities		(32,510)	(43,394)
Other, net		(5,964)	(12,971)
Net cash used in financing activities		(702,548)	(296,193)
Net decrease in cash and cash equivalents		(187,695)	(260,814)
Cash and cash equivalents at the beginning of the year		849,695	533,530
Effects of exchange rate changes on cash and cash equivalents		23,141	15,644
Cash and cash equivalents at the end of the period		685,141	288,359

See accompanying notes to condensed interim consolidated financial statements.

Notes to Condensed Interim Consolidated Financial Statements

1. Reporting Entity

Takeda Pharmaceutical Company Limited (the “Company”) is a public company incorporated in Japan. The Company and its subsidiaries (collectively, “Takeda”) is a global, values-based, R&D-driven biopharmaceutical company with a diverse portfolio, engaged primarily in the research, development, production and global commercialization of pharmaceutical products. Takeda’s principal pharmaceutical products include medicines in the following key business areas: gastroenterology (“GI”), rare diseases, Plasma-Derived Therapies (“PDT”) immunology, oncology, and neuroscience.

2. Basis of Preparation

(1) Compliance

Takeda has prepared the condensed interim consolidated financial statements in accordance with IAS 34 “Interim Financial Reporting” as issued by the International Accounting Standards Board (“IASB”).

The condensed interim consolidated financial statements do not contain all the information required in consolidated financial statements as of the end of a fiscal year. Therefore, the condensed interim consolidated financial statements should be used with the consolidated financial statements as of and for the fiscal year ended March 31, 2023.

(2) Approval of Financial Statements

Takeda’s condensed interim consolidated financial statements as of and for the nine-month period ended December 31, 2023 were approved on February 2, 2024 by Representative Director, President & Chief Executive Officer (“CEO”) Christophe Weber and Director & Chief Financial Officer Costa Saroukos.

(3) Functional and Presentation Currency

The condensed interim consolidated financial statements are presented in Japanese yen (“JPY”), which is the functional currency of the Company. All financial information presented in JPY has been rounded to the nearest JPY million, except when otherwise indicated. In tables with rounded figures, sums may not add up due to rounding.

(4) Use of Judgments, Estimates and Assumptions

The preparation of the condensed interim consolidated financial statements requires management to make certain judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities. Actual results could differ from these estimates.

These estimates and underlying assumptions are reviewed on a continuous basis. Changes in these accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

The condensed interim consolidated financial statements are prepared based on the same judgments and estimations as well as the accounting estimates and assumptions applied and described in Takeda’s consolidated financial statements as of and for the fiscal year ended March 31, 2023.

3. Material Accounting Policies

Material accounting policies adopted for the condensed interim consolidated financial statements are the same as those adopted for the consolidated financial statements as of and for the fiscal year ended March 31, 2023.

Takeda calculated income tax expenses for the nine-month period ended December 31, 2023, based on the estimated average annual effective tax rate.

4. Operating Segment and Revenue Information

Takeda comprises a single operating segment and is engaged in the research, development, manufacturing, marketing and out-licensing of pharmaceutical products. This is consistent with how the financial information is viewed in allocating resources, measuring performance, and forecasting future periods by the CEO who is Takeda's Chief Operating Decision Maker.

(1) Disaggregation of Revenue Information

Takeda's revenue from contracts with customers is comprised of the following:

Revenue by Type of Good or Service

	JPY (millions)	
	Nine-month Period Ended December 31,	
	2022	2023
Sales of pharmaceutical products	2,982,909	3,149,744
Out-licensing and service income	88,414	63,149
Total	3,071,322	3,212,893

	JPY (millions)	
	Three-month period ended December 31,	
	2022	2023
Sales of pharmaceutical products	1,068,509	1,089,062
Out-licensing and service income	28,042	22,124
Total	1,096,551	1,111,186

Revenue by Business Area and Product

	JPY (millions)	
	Nine-month Period Ended December 31,	
	2022	2023
Gastroenterology:		
ENTYVIO	547,888	619,291
TAKECAB/VOCINTI ⁽¹⁾	84,540	90,307
GATTEX/REVESTIVE	78,213	89,999
DEXILANT	55,106	36,117
PANTOLOC/CONTROLOC ⁽²⁾	33,777	35,520
ALOFISEL	1,984	2,556
Others	56,007	62,267
Total Gastroenterology	857,515	936,056
Rare Diseases:		
Rare Hematology:		
ADVATE	92,092	93,912
ADYNOVATE/ADYNOVI	49,860	51,235
FEIBA	32,593	28,911
VONVENDI	9,207	12,027
RECOMBINATE	9,667	8,957
Others	39,226	35,001
Total Rare Hematology	232,645	230,042

	JPY (millions)	
	Nine-month Period Ended December 31,	
	2022	2023
Rare Genetics and Other:		
TAKHZYRO	116,880	136,429
ELAPRASE	65,002	69,983
REPLAGAL	50,559	55,068
VPRIV	36,330	38,962
LIVTENCITY	7,312	13,948
Others	44,871	40,643
Total Rare Genetics and Other	320,954	355,033
Total Rare Diseases	553,600	585,075
PDT Immunology:		
immunoglobulin	390,483	485,696
albumin	85,508	94,265
Others	26,426	31,261
Total PDT Immunology	502,418	611,222
Oncology:		
ADCETRIS	65,785	84,244
LEUPLIN/ENANTONE	85,182	79,674
NINLARO	75,939	66,741
ICLUSIG	35,529	41,460
ALUNBRIG	15,764	21,120
VELCADE	24,735	4,138
EXKIVITY	2,250	3,357
Others	39,770	45,536
Total Oncology	344,953	346,269
Neuroscience:		
VYVANSE/ELVANSE	335,449	312,872
TRINTELLIX	79,699	80,226
Others	61,994	81,771
Total Neuroscience	477,141	474,868
Other:		
AZILVA ⁽¹⁾	56,590	29,055
FOSRENOL	10,906	11,135
Others	268,199	219,213
Total Other	335,695	259,403
Total	3,071,322	3,212,893

⁽¹⁾ The figures include the amounts of fixed dose combinations and blister packs.

⁽²⁾ Generic name: pantoprazole

	JPY (millions)	
	Three-month period ended December 31,	
	2022	2023
Gastroenterology:		
ENTYVIO	201,272	227,582
TAKECAB/VOCINTI ⁽¹⁾	29,845	31,528
GATTEX/REVESTIVE	29,779	31,108
DEXILANT	17,115	12,952
PANTOLOC/CONTROLOC ⁽²⁾	11,571	12,638
ALOFISEL	849	1,029
Others	20,693	22,352
Total Gastroenterology	311,124	339,189
Rare Diseases:		
Rare Hematology:		
ADVATE	29,724	31,208
ADYNOVATE/ADYNOVI	15,464	17,751
FEIBA	11,299	9,101
VONVENDI	3,308	4,594
RECOMBINATE	3,491	2,965
Others	13,642	11,702
Total Rare Hematology	76,928	77,321
Rare Genetics and Other:		
TAKHZYRO	44,053	49,337
ELAPRASE	22,589	24,312
REPLAGAL	16,251	18,862
VPRIV	12,990	14,632
LIVTENCITY	3,084	5,623
Others	15,479	14,017
Total Rare Genetics and Other	114,446	126,784
Total Rare Diseases	191,374	204,104
PDT Immunology:		
immunoglobulin	145,428	176,538
albumin	33,743	35,317
Others	9,269	10,987
Total PDT Immunology	188,440	222,843
Oncology:		
LEUPLIN/ENANTONE	31,525	30,896
ADCETRIS	24,070	29,972
NINLARO	27,120	20,399
ICLUSIG	12,312	14,449
ALUNBRIG	6,053	7,408
VELCADE	3,905	1,232
EXKIVITY	811	(110)
Others	13,865	16,862
Total Oncology	119,662	121,107

	JPY (millions)	
	Three-month period ended December 31,	
	2022	2023
Neuroscience:		
VYVANSE/ELVANSE	124,213	86,603
TRINTELLIX	29,901	29,258
Others	20,713	28,307
Total Neuroscience	174,827	144,167
Other:		
AZILVA ⁽¹⁾	19,405	5,374
FOSRENOL	3,380	2,998
Others	88,338	71,404
Total Other	111,124	79,776
Total	1,096,551	1,111,186

⁽¹⁾ The figures include the amounts of fixed dose combinations and blister packs.

⁽²⁾ Generic name: pantoprazole

(2) Geographic Information

Takeda's revenue from contracts with customers is based on the following geographic locations:

	JPY (millions)	
	Nine-month Period Ended December 31,	
	2022	2023
Japan	389,843	342,647
U.S.	1,621,772	1,685,498
Europe and Canada	632,403	721,538
Asia (excluding Japan)	169,024	188,779
Latin America	121,425	138,375
Russia/CIS	66,700	45,360
Other	70,156	90,696
Total	3,071,322	3,212,893

“Other” includes the Middle East, Oceania and Africa. This disaggregation provides revenue attributable to countries or regions based on the customer location.

	JPY (millions)	
	Three-month period ended December 31,	
	2022	2023
Japan	128,490	114,119
U.S.	589,246	580,736
Europe and Canada	223,438	261,570
Asia (excluding Japan)	63,306	65,503
Latin America	38,167	46,306
Russia/CIS	28,882	14,270
Other	25,021	28,682
Total	1,096,551	1,111,186

“Other” includes the Middle East, Oceania and Africa. This disaggregation provides revenue attributable to countries or regions based on the customer location.

5. Amortization and impairment losses on intangible assets associated with products

The impairment losses recorded for the nine-month period ended December 31, 2023 was JPY 119,307 million, which primarily include JPY 73,979 million impairment charges for ALOFISEL (for complex Crohn's perianal fistulas) following topline results of phase 3 ADMIRE-CD II trial and JPY 28,477 million impairment charges for EXKIVITY (for the treatment of non-small cell lung cancer) following a decision to initiate a voluntary withdrawal globally.

6. Other Operating Expenses

Other operating expenses were JPY 127,643 million and JPY 145,685 million for the nine-month period ended December 31, 2022 and 2023, respectively.

Other operating expenses for the nine-month period ended December 31, 2022 included the restructuring expenses JPY 38,473 million, pre-launch inventory write-offs JPY 18,984 million and write-off of option fees Takeda paid as part of collaboration agreements JPY 14,796 million.

Other operating expenses for the nine-month period ended December 31, 2023 included the restructuring expenses JPY 60,130 million, additional losses recorded for the supply agreement litigation with AbbVie, Inc. (AbbVie) in the current period JPY 25,339 million and loss from changes in the fair value of financial assets associated contingent consideration arrangements JPY 12,957 million.

7. Income Tax (Expenses) Benefit

Shire received a tax assessment from the Irish Revenue Commissioners (“Irish Revenue”) on November 28, 2018 for EUR 398 million. This assessment relates to the tax treatment of the USD 1,635 million break fee Shire received from AbbVie in connection with the terminated offer to acquire Shire made by AbbVie in 2014. Shire was acquired by Takeda in January 2019. Takeda appealed the assessment to the Tax Appeals Commission (“TAC”) and the appeal was heard by the TAC in late 2020. On July 30, 2021, Takeda received a ruling on the matter from the TAC, with the TAC ruling in favor of the Irish Revenue and recorded an income taxes payable for the case. Subsequently, on October 17, 2023, Takeda agreed with the Irish Revenue to settle the tax assessment for EUR 130 million including interest and without penalties, as a full and final settlement of all liabilities in relation to the receipt of the break fee. As a result, Takeda reversed its income taxes payable in excess of the settlement amount of EUR 130 million and recorded JPY 63,547 million reduction to tax expenses for the nine-month period ended December 31, 2023. Takeda made a payment in the settlement in the three-month period ended December 31, 2023.

The effective tax rate for the nine-month period ended December 31, 2023 was (46.7)% compared to 12.6% for the nine-month period ended December 31, 2022, mainly due to the tax expense reduction described above. This was partially offset by the tax charges from the write-down of deferred tax assets and legal entity restructuring for the nine-month period ended December 31, 2023.

8. Earnings per Share

The basis for calculating basic and diluted earnings per share (attributable to owners of the Company) is as follows:

	Nine-month Period Ended December 31,	
	2022	2023
Net profit for the period attributable to owners of the Company		
Net profit for the period attributable to owners of the Company (million JPY)	285,883	147,085
Net profit used for calculation of earnings per share (million JPY)	285,883	147,085
Weighted average number of ordinary shares outstanding during the period (thousands of shares) [basic]	1,550,992	1,563,101
Dilutive effect (thousands of shares)	14,243	15,575
Weighted average number of ordinary shares outstanding during the period (thousands of shares) [diluted]	1,565,235	1,578,676
Earnings per share		
Basic earnings per share (JPY)	184.32	94.10
Diluted earnings per share (JPY)	182.65	93.17

	Three-month Period Ended December 31,	
	2022	2023
Net profit for the period attributable to owners of the Company		
Net profit for the period attributable to owners of the Company (million JPY)	119,127	105,720
Net profit used for calculation of earnings per share (million JPY)	119,127	105,720
Weighted average number of ordinary shares outstanding during the period (thousands of shares) [basic]	1,554,524	1,568,902
Dilutive effect (thousands of shares)	15,892	16,217
Weighted average number of ordinary shares outstanding during the period (thousands of shares) [diluted]	1,570,416	1,585,118
Earnings per share		
Basic earnings per share (JPY)	76.63	67.38
Diluted earnings per share (JPY)	75.86	66.70

9. Bonds and Loans

(1) Bonds

During the nine-month period ended December 31, 2023, Takeda redeemed the following bonds.

Instrument	Issuance	Redemption date	Principal Amount in contractual currency	Type of redemption
USD Unsecured Senior Notes	September 2016	September 23, 2023	USD1,000 million	Maturity redemption
USD Unsecured Senior Notes	November 2018	November 26, 2023	USD500 million	Maturity redemption

(2) Loans

During the nine-month period ended December 31, 2023, Takeda entered into the following borrowing.

Instrument	Execution	Maturity	Principal Amount in contractual currency
Syndicated loans	April 2023	April 2030	JPY 100,000 million

During the nine-month period ended December 31, 2023, Takeda repaid the following borrowing.

Instrument	Execution	Repayment date	Principal Amount in contractual currency	Type of repayment
Syndicated loans	April 2016	April 26, 2023	JPY 100,000 million	Maturity repayment

10. Equity and Other Equity Items

(1) Disposal of treasury shares

During the nine-month period ended December 31, 2022, the Company conducted the disposal of 8,091 thousand treasury shares under the Long Term Incentive Plan (“LTIP”) for the Company Group employees overseas. The disposal of treasury shares resulted in a decrease in treasury shares of JPY 27,599 million.

During the nine-month period ended December 31, 2023, the Company conducted the disposal of 13,958 thousand treasury shares under the LTIP for the Company Group employees overseas. The disposal of treasury shares resulted in a decrease in treasury shares of JPY 47,614 million.

The Company's treasury shares were converted into the Company’s American Depositary Shares and settled with employees.

(2) Dividends

Dividends declared and paid	Total dividends declared and paid JPY (millions)	Dividends per share (JPY)	Record date	Effective date
April 1, 2022 to December 31, 2022				
Q1 2022	140,365	90.00	March 31, 2022	June 30, 2022
Q3 2022	140,474	90.00	September 30, 2022	December 1, 2022
April 1, 2023 to December 31, 2023				
Q1 2023	140,475	90.00	March 31, 2023	June 29, 2023
Q3 2023	148,037	94.00	September 30, 2023	December 1, 2023

11. Financial Instruments

(1) Fair Value Measurements

Derivative and non-derivative financial instruments measured at fair value are categorized in the following three-tier fair value hierarchy that reflects the significance of the inputs in making the measurements. Level 1 is defined as observable inputs, such as quoted prices in active markets for an identical asset or liability. Level 2 is defined as inputs other than quoted prices in active markets within Level 1 that are directly or indirectly observable. Level 3 is defined as unobservable inputs.

As of December 31, 2023	JPY (millions)			
	Level 1	Level 2	Level 3	Total
Assets:				
Financial assets measured at fair value through profit or loss				
Derivatives	—	22,770	7,311	30,081
Investments in convertible notes	—	—	10,997	10,997
Investments in debt instruments	—	—	1,113	1,113
Financial assets associated with contingent consideration arrangements	—	—	11,950	11,950
Derivatives for which hedge accounting is applied	—	44,299	—	44,299
Financial assets measured at fair value through OCI				
Trade and other receivables	—	104,931	—	104,931
Equity instruments	91,109	—	84,708	175,817
Total	91,109	172,000	116,079	379,188
Liabilities:				
Financial liabilities measured at fair value through profit or loss				
Derivatives	—	7,223	7,311	14,534
Financial liabilities associated with contingent consideration arrangements	—	—	8,321	8,321
Derivatives for which hedge accounting is applied	—	23,664	—	23,664
Total	—	30,886	15,632	46,518

(2) Valuation Techniques

The fair value of derivatives classified as Level 2 is measured based on Treasury management system valuation models or the Black-Scholes model, whose significant inputs are based on observable market data.

Derivatives classified as Level 3 include those recognized in connection with settlements of cash flows arising from differences between the fixed prices and floating market prices of renewable energy in a virtual power purchase agreement and those recognized in an agreement to offset the volatility of such cash flows. The fair value of derivatives in Level 3 is measured using the discounted cash flow method. The key assumptions taken into account include forecasted renewable energy prices and the expected generation of the renewable energy generating facility.

The fair value of the investment in convertible notes is measured using techniques such as the discounted cash flow and option pricing models.

The fair value of trade and other receivables, which are due from customers that Takeda has the option to factor, are measured based on the invoiced amount.

Equity investments and investments in debt instruments are not held for trading. If equity instruments or investments in debt instruments are quoted in an active market, the fair value is based on price quotations at the period-end-date. If equity instruments or investments in debt instruments are not quoted in an active market, the fair value is calculated utilizing an adjusted book value per share method or EBITDA multiples approach based on available information as of each period-end-date and comparable companies. The principal input that is not observable and utilized for the calculation of the fair value of equity instruments and investments in debt instruments classified as Level 3 is the EBITDA rate used for the EBITDA multiples approach, which ranges from 4.1 times to 12.4 times.

Financial assets and liabilities associated with contingent consideration arrangements are measured at fair value at the time of the divestiture or the acquisition date of business combination. When the contingent consideration arrangement meets the definition of a financial asset or liability, it is subsequently re-measured at fair value at each closing date. The determination of the fair value is based on models such as scenario-based methods and discounted cash flows. The key assumptions take into consideration the probability of meeting each performance target, forecasted revenue projections, and the discount factor. The financial assets associated with contingent consideration arrangements are recognized mainly in relation to the divestiture of XIIDRA. The financial liabilities associated with contingent consideration arrangements are discussed in Note (5) Financial liabilities associated with contingent consideration arrangements.

(3) Transfers between levels

Takeda recognizes transfers between levels of the fair value hierarchy, at the end of the reporting period during which the change has occurred. There were transfers from Level 3 to Level 1 recorded in the nine-month period ended December 31, 2023. These transfers resulted from the investments in the companies whose shares were previously not listed on an equity or stock exchange and had no recent observable active trades in the shares. During the nine-month period ended December 31, 2023, the companies listed their equity shares on an exchange and are currently actively traded in the market. As the equity shares have a published price quotation in an active market, the fair value measurement was transferred from Level 3 to Level 1 on the fair value hierarchy during the nine-month period ended December 31, 2023. There were no other significant transfers between levels of the fair value hierarchy during the nine-month period ended December 31, 2023.

(4) Level 3 fair values

Takeda invests in equity instruments mainly for research collaboration. The following table shows a reconciliation from the opening balances to the closing balances for Level 3 financial asset fair values for the nine-month period ended December 31, 2023. The disclosure related to Level 3 financial liabilities which are financial liabilities associated with contingent consideration arrangements are included in (5) Financial liabilities associated with contingent consideration arrangements. There are no significant changes in fair value during the changes in certain assumptions which influence the fair value measurement for Level 3 financial assets.

	JPY (millions)	
	Nine-month Period Ended December 31, 2023	
	Financial assets associated with contingent consideration arrangements	Equity instruments
As of the beginning of the period	23,806	83,236
Changes recognized as finance income or finance expenses	(600)	—
Changes in fair value of financial assets associated with contingent consideration due to other elements than time value	(12,957)	—
Changes in fair value of financial assets measured at fair value through OCI and exchange differences on translation of foreign operations	1,701	574
Purchases	—	1,691
Sales	—	(1)
Transfers to Level 1	—	(5,022)
Acquisition from conversion of convertible notes	—	4,230
As of the end of the period	<u>11,950</u>	<u>84,708</u>

(5) Financial liabilities associated with contingent consideration arrangements

Financial liabilities associated with contingent consideration arrangements represent consideration related to business combinations or license agreements that are payable only upon future events such as the achievement of development milestones and sales targets, including pre-existing contingent consideration arrangements of the companies that are acquired by Takeda. At each reporting date, the fair value of financial liabilities associated with contingent consideration arrangements is re-measured based on risk-adjusted future cash flows discounted using an appropriate discount rate.

As of December 31, 2023, the balance primarily relates to pre-existing contingent consideration arrangements from historical acquisitions.

The fair value of financial liabilities associated with contingent consideration arrangements could increase or decrease due to changes in certain assumptions which underpin the fair value measurements. The assumptions include probability of milestones being achieved.

The fair value of financial liabilities associated with contingent consideration arrangements are classified as Level 3 in the fair value hierarchy. The following table shows a reconciliation from the opening balances to the closing balances for financial liabilities associated with contingent consideration arrangements for the nine-month period ended December 31, 2023. There are no significant changes in fair value during the changes in significant assumptions which influence the fair value measurement for financial liabilities associated with contingent consideration arrangements.

	JPY (millions)
	Nine-month Period Ended December 31, 2023
As of the beginning of the period	8,139
Changes in the fair value during the period	27
Foreign currency translation differences	155
As of the end of the period	<u>8,321</u>

(6) Financial instruments not measured at fair value

The carrying amount and fair value of financial instruments that are not measured at fair value in the condensed interim consolidated statements of financial position are as follows. Fair value information is not provided for financial instruments, if the carrying amount is a reasonable estimate of fair value due to the relatively short period of maturity of these instruments.

	JPY (millions)	
	As of December 31, 2023	
	Carrying amount	Fair value
Bonds	3,607,636	3,307,319
Long-term loans	736,236	733,090

Long-term financial liabilities are recognized at their carrying amount. The fair value of bonds is measured at quotes whose significant inputs to the valuation model used are based on observable market data. The fair value of loans is measured at the present value of future cash flows discounted using the applicable market rate on the loans in consideration of the credit risk by each group classified in a specified period. The fair value of bonds and long-term loans are classified as Level 2 in the fair value hierarchy.

12. Commitments and Contingent Liabilities

Litigation

Takeda is involved in various legal and administrative proceedings. There were no significant updates during the nine-month period ended December 31, 2023, except for the matters below.

Sales, Marketing, and Regulation

COLCRYS Antitrust Litigation

In September 2021, an antitrust class action was filed against Takeda Pharmaceuticals U.S.A., Inc. (“Takeda”) in the U.S. District Court for the Eastern District of Pennsylvania. The plaintiffs, a putative class of wholesalers, allege that settlements that Takeda entered into in 2015 and 2016 to resolve patent litigation claims against several generic drug manufacturers related to generic formulations of COLCRYS were anticompetitive. In September 2023, Takeda reached an agreement in principle to resolve the antitrust matter for an amount that is immaterial, which was fully executed in December 2023. The settlement had no material impact on Takeda’s condensed interim consolidated statements of profit or loss.

AbbVie Supply Agreement Litigation

In November 2020, AbbVie brought suit against Takeda Pharmaceutical Company Limited (“Takeda”) in Delaware Chancery Court alleging Takeda breached its agreement with AbbVie related to the supply of LUPRON in the U.S. due to shortages arising from quality issues the U.S. Food & Drug Administration identified concerning Takeda’s production facility in Hikari, Japan as part of a Form 483 issued in November 2019 and a Warning Letter issued in June 2020. In the litigation, AbbVie sought both preliminary injunctive relief and monetary damages. In September 2021, the court issued an order denying AbbVie’s request for injunctive relief. The court subsequently issued a decision finding Takeda in breach of the supply agreement. In September 2023, the court issued a decision regarding the quantification of AbbVie’s monetary damages and subsequently entered judgment in December 2023. In accordance with the judgment, Takeda will pay USD 506 million, including interest, in April 2024. Takeda had established a provision against this case during the course of the litigation and, as a result of the court’s September 2023 decision, recorded an additional JPY 25,339 million loss in other operating expenses and JPY 6,577 million in finance expenses for the interest for the nine-month period ended December 31, 2023.

Investigation of Patient Assistance Programs

In June 2019, the DOJ (through the U.S. Attorney’s Office in Boston) issued a subpoena to Shire Pharmaceuticals LLC, which was acquired by Takeda during the year ended March 31, 2019 (through Takeda’s acquisition of Shire plc). The subpoena generally seeks information about Shire’s interactions with 501(c)(3) organizations that provide financial assistance to Medicare patients taking Shire drugs, including the hereditary angioedema medications FIRAZYR and CINRYZE. Takeda was cooperating with the investigation and in December 2023, Takeda reached a settlement for an amount that is immaterial. The settlement had no material impact on Takeda’s condensed interim consolidated statements of profit or loss.

13. Subsequent Events

Not applicable.

2. Others

Interim Dividend

In accordance with the provision of Article 29 of the Articles of Incorporation of the Company, Takeda made the following resolution on an interim dividend for the 147th fiscal year (from April 1, 2023 to March 31, 2024) at the meeting of the Board of Directors held on October 26, 2023, and paid the interim dividend.

(a) Total amount of interim dividends	JPY 148,037,012,490
(b) Interim dividend per share	JPY 94.00
(c) Effective date/ Payment start date	December 1, 2023

B. Information on Guarantors of the Company

Not applicable.